April 11, 2025

Dentsply Sirona
Laura Sorbin
Sr. Technical RA Manager
221 West Philadelphia Street Suite 60W
York, Pennsylvania 17401

Re: K250081
Trade/Device Name: Atlantis® Abutments in Titanium
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 8, 2025
Received: January 13, 2025

Dear Laura Sorbin:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -S

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250081

Device Name
Atlantis® Abutments in Titanium

Indications for Use *(Describe)*

Atlantis Abutment & Atlantis Abutment Milling
The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.

Atlantis Crown Abutment
The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant.

Atlantis Conus Abutment
The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant.

Atlantis Healing Abutment
The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant.

Implant Manufacturer: Dentsply Sirona
Implant System: OsseoSpeed/OsseoSpeed TX
Implant Diameter (in mm): 3.0 (Yellow), 3.5, 4.0 (Aqua), 4.5, 5.0 (Lilac), 4.0 (Blue - Previous)
Abutment Platform Diameter (in mm): 2.330 (Yellow), 2.866 (Aqua), 3.865 (Lilac), 3.368 (Blue - Previous)

Implant Manufacturer: MIS Implant Technologies Inc.
Implant System: V3 (NP, SP), C1 (NP, SP, WP)
Implant Diameter (in mm): V3: 3.30 (NP), 3.90, 4.3, 5.0 (SP); C1: 3.30 (NP), 3.75, 4.2 (SP), 5.0 (WP)
Abutment Platform Diameter (in mm): V3: 2.765 (NP), 3.16 (SP); C1: 2.76 (NP), 3.16 (SP), 4.01 (WP)

Implant Manufacturer: Altatec GmbH
Implant System: Conelog Screw-Line Implant
Implant Diameter (in mm): 3.3, 3.8, 4.3, 5.0
Abutment Platform Diameter (in mm): 2.80 (3.3), 3.00 (3.8, 4.3), 3.80 (5.0)

Implant Manufacturer: Nobel Biocare
Implant System: NobelActive
Implant Diameter (in mm): 3.0
Abutment Platform Diameter (in mm): 2.461
Implant System: Branemark System (NP, RP, WP)
Implant Diameter (in mm): 3.3 (NP), 3.75, 4.0 (RP), 5.0, 5.5 (WP)

Abutment Platform Diameter (in mm): 3.476 (NP), 4.069 (RP), 5.033 (WP)

Implant Manufacturer: BioHorizons
Implant System: Prodigy System Internal/Tapered Internal
Implant Diameter (in mm): 3.5, 4.5, 5.7
Abutment Platform Diameter (in mm): 3.434 (3.5), 4.399 (4.5), 5.644 (5.7)
Implant System: Maestro
Implant Diameter (in mm): 3.5, 4.0, 5.0
Abutment Platform Diameter (in mm): 3.708 (3.5), 4.242 (4.0), 5.258 (5.0)

Implant Manufacturer: Biomet 3i
Implant System: Certain, Certain Prevail, Certain XP
Implant Diameter (in mm): Certain: 3.25, 4, 5, 6; Certain Prevail: 3.4, 4, 5; Certain XP: 5, 6
Abutment Platform Diameter (in mm): 3.404 (3.25, 3.4), 4.012 (4), 4.942 (5), 5.951 (6)
Implant System: Osseotite Tapered and Osseotite Parallel Walled
Implant Diameter (in mm): 3.25, 3.75, 4.0, 5.0, 6.0
Abutment Platform Diameter (in mm): 4.056 (3.25, 3.75, 4.0), 4.978 (5.0), 5.985 (6.0)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY
for
Atlantis® Abutments in Titanium (K250081)

1. Submitter Information:

Dentsply Sirona
221 West Philadelphia Street
Suite 60W
York, PA 17401, USA

Contact Person: Laura Sobrin
Telephone Number: 717-849-4434
Email: laura.sobrin@dentsplysirona.com
Date Prepared: April 11, 2025

2. Device Name:
   - Proprietary Name: Atlantis® Abutments in Titanium
   - Classification Name: Abutment, Implant, Endosseous, Root-Form
   - CFR Number: 872.3630
   - Device Class: Class II
   - Primary Product Code: NHA

3. Predicate/Reference Devices:

The primary purpose of the Bundled Traditional 510(k) premarket notification is to modify the labeling of the Atlantis® Abutments in Titanium to update the safety in an MR environment to indicate MR Conditional. This includes a total of 11 implant system compatibilities/clearances.

The predicate device, K193529, which is an Atlantis® Abutment specifically compatible with the MIS Conical Connection implant system, represents the most recently cleared implant system compatibility for the Atlantis® Abutments in Titanium.

The 510(k) clearances for the additional implant system compatibilities bundled in this submission are referred to as reference devices. Therefore, the proposed devices are modifications to the predicate device, K193529, and modification to the additional 10 implant system compatibilities/clearances, reference devices, listed below.

Predicate Device Name – Implant system compatibility included in this submission for MR Conditional labeling update	510(k)	Product Code and Classification Reg	Company Name
Atlantis® Abutment for MIS Conical Connection Implants	K193529	NHA, Abutment, Implant, Dental, Endosseous 872.3630, Endosseous dental implant abutment	Dentsply Sirona Inc.

Reference Device Name – Additional implant system compatibilities bundled in this submission for MR Conditional labeling update	510(k)	Product Code and Classification Reg	Company Name
Atlantis® Abutment for Conelog Implant	K161030	NHA, 872.3630	Dentsply Sirona Inc.
Atlantis® Abutment for NobelActive 3.0	K151039	NHA, 872.3630	Dentsply Sirona Inc.
Atlantis® Abutments for Astra Osseospeed 3.0 Implant System (currently marketed as OsseoSpeed/OsseoSpeed TX)	K081666	NHA, 872.3630	Astra Tech Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for BioHorizons Implant	K073258	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for Astra Implant (currently marketed as OsseoSpeed/OsseoSpeed TX)	K070833	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for 3i Certain MicroMini Implant	K062197	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for 3i MicroMini Implant (also cleared compatibility with Branemark NP and BioHorizons NP)	K062069	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for Astra Implant (currently marketed as OsseoSpeed/OsseoSpeed TX)	K051652	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.
Atlantis® Abutment for 3i Certain Implant	K051011	NHA, 872.3630	Atlantis Components Inc., now Dentsply Sirona Inc.
Atlantis® Abutment and Atlantis® Abutment Screw (cleared compatibility with Biomet Osseotite, Branemark RP/WP, and BioHorizons RP/WP)	K981858	DZE, Implant, endosseous, root-form* 872.3640, Endosseous dental implant	Atlantis Components Inc., now Dentsply Sirona Inc.

*This is an older 510(k) where the Atlantis® Abutment was cleared under product code DZE, Implant, Endosseous, Root-form

In addition to the above reference devices, the below reference devices are added to close the gap in technological characteristic differences between the predicate device and the proposed modified Atlantis® Abutment in Titanium implant system compatibilities.

Reference Device Name	510(k)	Product Code & Classification Reg	Company Name	Reason for inclusion
OmniTaper EV Dental Implants; DS Implants with EV connection DS Implants abutments with EV Connection	K221094	DZE, 872.3640 NHA, 872.3630	Dentsply Sirona Inc.	Reference to MR testing on worst-case implants/abutments devices Reference to same reprocessing instructions (reference device TiDesign EV)
Atlantis® Suprastructures	K151439	NHA, 872.3630	Dentsply Sirona Inc.	Similar Angulated Screw Access (ASA) feature
3Shape Abutment Designer Software	K151455	PNP, 872.3630	3Shape A/S	The 3Shape software is part of the additional proposed workflow that allows the user to design the Atlantis Abutment within the Atlantis design limitations prior to manufacturing by Dentsply Sirona.

4. Description of Device:

Atlantis® Abutment in Titanium refers to the following abutments that are the subject of this 510(k):

- Atlantis® Abutment,
- Atlantis® Crown Abutment,
- Atlantis® Conus Abutment, and
- Atlantis® Healing Abutment.

The Atlantis® Abutments in Titanium are patient-specific dental abutments that are intended for attachment to dental implants in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The design of the Atlantis® Abutments in Titanium is derived from patient dental models and is completed by Dentsply Sirona using computer-assisted design (CAD) technology according to the clinician's prescription. The final CAD design of the Atlantis® Abutment in Titanium is fabricated using computer-assisted manufacturing (CAM) to produce a customized, patient-specific device. Design and fabrication of the Atlantis® Abutment in Titanium is completed in internal Dentsply Sirona manufacturing facilities.

Alternatively, the CAD design, according to the clinician's prescription, can be performed by a laboratory or clinician in an FDA cleared abutment design software (3Shape Abutment Designer Software, K151455) within the design envelope of the Atlantis® Abutments which is codified in the validated and locked design library of the cleared software. Fabrication of the Atlantis® Abutment is then completed in internal Dentsply Sirona manufacturing facilities.

The Atlantis® Abutment in Titanium serves as a connection of the prosthetic construction and the endosseous implant. The lower part of the abutment is designed to fit with the specific implant geometry it is compatible, and the upper part design is according to the patient's specific anatomy. The Atlantis® Abutment in Titanium, including the Conus abutments and Healing abutments, are available in Titanium or Gold-shaded Titanium (titanium nitride layer applied using PVD (Physical Vapor Deposition)). The Crown Abutment is only available in Titanium.

The Atlantis® Abutment design envelope became the basis for the other more specific designs that make up the Atlantis® Abutments in Titanium. The Atlantis® Abutment is intended for use with an endosseous implant and for single tooth restoration.

The Atlantis® Crown Abutment in Titanium incorporates a design that is a combination of an abutment and an anatomically accurate crown to constitute the final finished device. It functions as a substructure that also serves as the final abutment, in a partially or completely edentulous patient.

The Atlantis® Conus abutment supports a removable prosthesis (bridges and overdentures) which is retained by friction fit to the abutment. The abutment connects to the prosthesis via caps embedded in the prosthesis.

The Atlantis® Healing Abutment is used with the compatible implants for temporary use during soft tissue healing after one-stage and two-stage surgeries. It is designed based on the planned final Atlantis® Abutment or Atlantis® Crown Abutment, using the same emergence profile as those abutments to achieve an aesthetic outcome during the soft tissue healing phase.

Unless otherwise noted in this summary, the design envelope has remained unchanged from the previously cleared systems. Parameters such as gingival height and abutment diameter are dependent on the different implant system compatibilities.

Table 4.1 below includes the main specifications of the Atlantis® Abutments in Titanium that are subject of this submission.

Table 4.1 Specifications of the Atlantis® Abutments in Titanium that are subject of this submission

Item	Specification
Atlantis® Abutment in Titanium for MIS V3 and C1 implants	
Abutment platform diameter	Ø2.765, 2.76, 3.16, 4.01 mm
Compatible Implant diameter	V3: Ø3.3, 3.9, 4.3, 5.0 mm; C1: Ø3.3, 3.75, 4.2, 5.0 mm
Compatible Implant System	MIS V3 (K163349), MIS C1 (K172505)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for Conelog implants	
Abutment platform diameter	Ø2.80, 3.00, 3.80 mm
Compatible Implant diameter	Ø 3.3, 3.8, 4.3, 5.0 mm
Compatible Implant System	Conelog Screw-Line Implant 3.3, 3.8/4.3, 5.0 (K113779)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for Nobel Active 3.0 implants	
Abutment platform diameter	Ø2.461 mm
Compatible Implant diameter	3.0 mm
Compatible Implant System	Nobel Biocare Active Implant 3.0 (K102436)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for OsseoSpeed 3.0 implants	
Abutment platform diameter	Ø2.330 mm
Compatible Implant Diameter	Ø 3.0 mm
Compatible Implant System	OsseoSpeed 3.0 – Yellow, OsseoSpeed TX 3.0 - Yellow (K080396, K101732)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for BioHorizons implants	
Abutment platform diameter	Ø3.434, 4.399, 5.644 mm
Compatible Implant Diameter	3.5, 4.5, 5.7 mm
Compatible Implant System	BioHorizons Internal 3.5, 4.5, 5.7 (K042429)
Connection	Internal Hex, Tapered Internal
Atlantis® Abutment in Titanium for OsseoSpeed 3.5 and 4.0 mm implants	
Abutment platform diameter	Ø2.866 mm
Compatible Implant Diameter	3.5, 4.0 mm

Item	Specification
Compatible Implant System	OsseoSpeed 3.5/4.0 – Aqua, OsseoSpeed TX 3.5/4.0 - Aqua (K053384, K101732)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for Biomet 3i Certain implants	
Abutment platform diameter	Ø3.404 mm
Compatible Implant Diameter	3.25, 3.4 mm
Compatible Implant System	Biomet 3i Certain 3.25, 4/3, Biomet 3i Certain Prevail 3/4/3 (3.4), 4/3 (K051461)
Connection	Internal Hexagon Connection
Atlantis® Abutment in Titanium for Biomet, Nobel Biocare, and BioHorizons implants	
Abutment platform diameter	Biomet: Ø 4.056 mm Nobel: Ø 3.476 mm BioHorizons: 3.708 mm
Compatible Implant Diameter	Biomet: 3.25, 3.75, 4.0 mm Nobel: 3.3 mm BioHorizons: 3.5 mm
Compatible Implant System	3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458)
Connection	External Hexagon Connection
Atlantis® Abutment in Titanium for Osseospeed/Osseospeed TX implants	
Abutment platform diameter	Ø 3.368, 3.865 mm
Compatible Implant Diameter	Ø 4.0, 4.5, 5.0 mm
Compatible Implant System	OsseoSpeed 4.0 Blue (Previous) (K041492) OsseoSpeed/OsseoSpeed TX 4.5, 5.0 – Lilac (K053384, K101732)
Connection	Internal Conical Connection
Atlantis® Abutment in Titanium for 3i Certain implants	
Abutment platform diameter	Ø 4.012, 4.942, 5.951 mm
Compatible Implant Diameter	Ø 4.0, 5.0, 6.0 mm
Compatible Implant System	Biomet 3i Certain 4.0, 5.0, 6.0, 5/4, Biomet 3i Certain Prevail 4/5/4, 5/6/5, 5/4, 6/5, Biomet Certain XP 4/5, 5/6 (K031475)
Connection	Internal hexagon connection
Atlantis® Abutment in Titanium for Biomet, Nobel Biocare, and BioHorizons implants	
Abutment platform diameter	Biomet: 4.056, 4.978, 5.985 mm Nobel: 4.069, 5.033 mm BioHorizons: 4.242, 5.258 mm
Compatible Implant Diameter	Biomet: 3.75, 4.0, 5.0, 6.0 mm Nobel: 3.75, 4.0, 5.0, 5.5 mm BioHorizons: 4.0, 5.0 mm
Compatible Implant System	Biomet 3i Osseotite 3.75, 4.0, 5.0, 6.0, Biomet Osseotite XP 4/5, 5/6 (K983347) Branemark RP 3.75 and 4.0, Branemark WP 5.0 and 5.5, (K974828, K022562) BioHorizons External 4.0 and 5.0 (K972313)
Connection	External Hexagon Connection

5. Intended Use and Indications for Use:

   The proposed devices and the predicate device, Atlantis® Abutment for MIS Conical Connection Implants (K193529), have the same intended use. The proposed devices are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.

   The Indications for Use of the proposed devices are similar to those of the predicate device. Refer to Table 5.1 for a comparison.

   Table 5.2 includes additional tables that provide a comparison between the originally cleared Indications for Use and the proposed Indications for Use statement for each implant system compatibility, and a discussion on the differences.

Table 5.1: Comparison of the Intended Use/Indications for Use of the Proposed Devices Atlantis® Abutments in Titanium and the Predicate Device (K193529)

Item	Proposed Devices Atlantis® Abutments in Titanium	Predicate Device Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Discussion
Intended use	Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.	Dental implant abutments are intended to be used in the upper or lower jaw for supporting tooth replacements to restore chewing function.	Same
Indications for Use	Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries.	The Atlantis® Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented, or screw retained to the abutment. The abutment screw is intended to secure the Atlantis® Abutment to the endosseous implant. The Atlantis® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the Atlantis® Crown Abutment to the endosseous implant. The Atlantis® Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the Atlantis® Conus Abutment to the endosseous implant. The Atlantis® Healing Abutment can be used with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The abutment screw is intended to secure the	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). "The prosthesis can be cemented, or screw retained to the abutment." was removed as a crown cannot be screwed to an abutment. Restorations are always cemented to an abutment. The consolidated Indications for Use include each implant system compatibility information by implant system manufacturer.

Item	Proposed Devices Atlantis® Abutments in Titanium	Predicate Device Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Discussion
	The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: Dentsply Sirona Implant System: OsseoSpeed/OsseoSpeed TX Implant Diameter (in mm): 3.0 (Yellow), 3.5, 4.0 (Aqua), 4.5, 5.0 (Lilac), 4.0 (Blue - Previous) Abutment Platform Diameter (in mm): 2.330 (Yellow), 2.866 (Aqua), 3.865 (Lilac), 3.368 (Blue - Previous) Implant Manufacturer: MIS Implant Technologies Inc. Implant System: V3 (NP, SP), C1 (NP, SP, WP) Implant Diameter (in mm): V3: 3.30 (NP), 3.90, 4.3, 5.0 (SP); C1: 3.30 (NP), 3.75, 4.2 (SP), 5.0 (WP) Abutment Platform Diameter (in mm): V3: 2.765 (NP), 3.16 (SP); C1: 2.76 (NP), 3.16 (SP), 4.01 (WP) Implant Manufacturer: Altatec GmbH Implant System: Conelog Screw-Line Implant Implant Diameter (in mm): 3.3, 3.8, 4.3, 5.0 Abutment Platform Diameter (in mm): 2.80 (3.3), 3.00 (3.8, 4.3), 3.80 (5.0) Implant Manufacturer: Nobel Biocare Implant System: NobelActive Implant Diameter (in mm): 3.0 Abutment Platform Diameter (in mm): 2.461 Implant System: Branemark System (NP, RP, WP) Implant Diameter (in mm): 3.3 (NP), 3.75, 4.0 (RP), 5.0, 5.5 (WP) Abutment Platform Diameter (in mm): 3.476 (NP), 4.069 (RP), 5.033 (WP) Implant Manufacturer: BioHorizons Implant System: Prodigy System Internal/Tapered Internal Implant Diameter (in mm): 3.5, 4.5, 5.7	Atlantis® Healing Abutment to the endosseous implant. Atlantis® Abutment is compatible with MIS Conical Connection implant from MIS Implant System. Atlantis® products are compatible with the implants shown in the table below. Implant manufacturer – MIS-IMPLANT TECHNOLOGIES INC Trade Name- Abutment Platform Diameter – Implant Diameter Atlantis Abutment for MIS V3 NP - Ø2.765mm -V3: Ø3.30 mm Atlantis Abutment for MIS C1 NP - Ø2.76mm - C1: Ø3.30 mm Atlantis Abutment for MIS C1 & V3 SP - Ø3.16mm - C1: Ø3.75,4.2 mm, V3: Ø3.90,4.3,5.0 mm Atlantis Abutment for MIS C1 WP - Ø4.01mm C1: Ø5.0 mm	

Item	Proposed Devices Atlantis® Abutments in Titanium	Predicate Device Atlantis® Abutment for MIS Conical Connection Implants (K193529)	Discussion
	Abutment Platform Diameter (in mm): 3.434 (3.5), 4.399 (4.5), 5.644 (5.7) Implant System: Maestro Implant Diameter (in mm): 3.5, 4.0, 5.0 Abutment Platform Diameter (in mm): 3.708 (3.5), 4.242 (4.0), 5.258 (5.0) Implant Manufacturer: Biomet 3i Implant System: Certain, Certain Prevail, Certain XP Implant Diameter (in mm): Certain: 3.25, 4, 5, 6; Certain Prevail: 3.4, 4, 5; Certain XP: 5, 6 Abutment Platform Diameter (in mm): 3.404 (3.25, 3.4), 4.012 (4), 4.942 (5), 5.951 (6) Implant System: Osseotite Tapered and Osseotite Parallel Walled Implant Diameter (in mm): 3.25, 3.75, 4.0, 5.0, 6.0 Abutment Platform Diameter (in mm): 4.056 (3.25, 3.75, 4.0), 4.978 (5.0), 5.985 (6.0)		

Table 5.2: Comparison between the originally cleared Indications for Use and the proposed Indications for Use statement for each Atlantis Abutments in Titanium

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
K193529	The ATLANTIS® Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS® Abutment to the endosseous implant. The ATLANTIS® Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS® Crown Abutment to the endosseous implant. The ATLANTIS® Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS® Conus Abutment to the endosseous implant. The ATLANTIS® Healing Abutment can be used with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The abutment screw is intended to secure the ATLANTIS® Healing Abutment to the endosseous implant. ATLANTIS® Abutment is compatible with MIS Conical Connection implant from MIS Implant System.	Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). Removed incorrect statement around "The prosthesis [crown] can be cemented or screw retained to the abutment". This was removed because a crown cannot be screwed to an abutment. Crowns are always cemented to an abutment.

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	ATLANTIS® products are compatible with the implants shown in the table below. Implant manufacturer - MIS-IMPLANT TECHNOLOGIES INC Trade Name- Abutment Platform Diameter-Implant Diameter Atlantis Abutment for MIS V3 NP - Ø2.765mm -V3: Ø3.30 mm Atlantis Abutment for MIS Cl NP - Ø2.76mm - Cl: Ø3.30 mm Atlantis Abutment for MIS C1 & V3 SP - Ø3. l 6mm - Cl: Ø3.75,4.2 mm, V3: Ø3.90,4.3,5.0 mm Atlantis Abutment for MIS Cl WP - Ø4.01 mm - Cl: Ø5.0 mm	two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: MIS Implant Technologies Inc. Implant System: V3 (NP, SP), C1 (NP, SP, WP) Implant Diameter (in mm): V3: 3.30 (NP), 3.90, 4.3, 5.0 (SP); C1: 3.30 (NP), 3.75, 4.2 (SP), 5.0 (WP) Abutment Platform Diameter (in mm): V3: 2.765 (NP), 3.16 (SP); C1: 2.76 (NP), 3.16 (SP), 4.01 (WP)	
K161030	The ATLANTIS™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS Abutment to the endosseous implant. The ATLANTIS™ Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS Crown Abutment to the endosseous implant. The ATLANTIS™ Conus Abutment is intended for	Atlantis Abutment & Atlantis Abutment Milling The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). Removed incorrect statement around "The prosthesis [crown] can be cemented or screw retained to the abutment". This was removed because a crown cannot be screwed to an abutment. Crowns are always cemented to an abutment. Added Healing Abutment indications.

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment-retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS Conus Abutment to the endosseous implant. ATLANTIS™ products are compatible with the implants shown in the table below. Implant Manufacturer - Trade Name - Implant Diameter - Abutment Platform Diameter Altatec GmbH CONELOG SCREW-LINE Implant Ø3.3, 3.8, 4.3, 5.0 mm Ø3.3, 3.8, 4.3, 5.0 mm	screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: Altatec GmbH Implant System: Conelog Screw-Line Implant Implant Diameter (in mm): 3.3, 3.8, 4.3, 5.0 Abutment Platform Diameter (in mm): 2.80 (3.3), 3.00 (3.8, 4.3), 3.80 (5.0)	Correction was made to the abutment platform diameter since the original indications repeated the implant diameter measurements instead of specifically referring to the abutment platform diameter measurements.
K151039	The ATLANTIS™ Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cemented or screw retained to the abutment. The abutment screw is intended to secure the ATLANTIS™ Abutment to the endosseous implant. The ATLANTIS™ Crown Abutment is intended for	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). Removed incorrect statement around "The prosthesis [crown] can be cemented or screw retained to the

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The abutment screw is intended to secure the ATLANTIS™ Crown Abutment to the endosseous implant. The ATLANTIS™ Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is attachment retained by friction fit to the abutment. The abutment screw is intended to secure the ATLANTIS™ Conus Abutment to the endosseous implant. ATLANTIS™ Abutment for NobelActive 3.0 is compatible with the NobelActive 3.0 implant.	The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: Nobel Biocare Implant System: NobelActive Implant Diameter (in mm): 3.0 Abutment Platform Diameter (in mm): 2.461	abutment". This was removed because a crown cannot be screwed to an abutment. Crowns are always cemented to an abutment. Added the abutment platform diameter information to be consistent with the more recent Atlantis Abutment clearances. Added Healing Abutment indications. Although this specific implant system compatibility does not have a Conus Abutment (Conus Abutment was cleared but now discontinued), the Atlantis Conus Abutment is still included in the general indications as all Atlantis Abutments in Titanium share the same indications and Instructions for Use. The user will refer to the compatibility chart to confirm which abutments are available with which implant system.
K081666	The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the maxillary lateral incisors and mandibular lateral and central incisors. The	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. This device is compatible with the Astra Tech OsseoSpeed 3.0 mm Implant. Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the Implant.	or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: Dentsply Sirona Implant System: OsseoSpeed/OsseoSpeed TX Implant Diameter (in mm): 3.0 (Yellow) Abutment Platform Diameter (in mm): 2.330 (Yellow)	3Shape software (K151455). Removed the statement around “The prosthesis [crown] can be cemented retained to the abutment”. This was removed as this is redundant since crowns are always cemented to an abutment. Added the abutment platform diameter information to be consistent with the more recent Atlantis Abutment clearances. Added Healing Abutment, Conus Abutment, and Crown Abutment indications. This abutment is not offered as a Conus Abutment. However, all Atlantis Abutments in Titanium share the same indications and Instructions for Use. The user will refer to the compatibility chart to confirm which abutments are available with which implant system. Limitations for use statement (“limited to maxillary lateral incisors and mandibular lateral and central incisors”) specific to small diameters such as the Atlantis Abutment for OsseoSpeed/OsseoSpeed TX 3.0 are now partially captured in the Contraindications section of the Instructions for Use. In addition, this limitation for use is fully captured in the implant system Indications for Use (K080396, K101732). The implant system indications and placement

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
			limitations dictate where the abutment will be placed. Therefore, the limitations for use are not repeated in the indications. The special note was removed altogether for the following reasons: - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the Contraindications section of the Instructions for Use.
K073258	The Atlantis Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. This device is compatible with the following manufacturers' implant systems: BioHorizons The Prodigy System^{Tm} Dental Implants 3.5mm, 4.0mm, 5.0mm and 6.0mm Implants. Please note: This device may be used in an early load situation,but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). Removed the statement around “The prosthesis [crown] can be cemented retained to the abutment”. This was removed as this is redundant since crowns are always cemented to an abutment. Added the abutment platform diameter information to be consistent with the more recent Atlantis Abutment clearances. Added Healing Abutment, Conus Abutment, and Crown Abutment

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: BioHorizons Implant System: Prodigy System Internal/Tapered Internal Implant Diameter (in mm): 3.5, 4.5, 5.7 Abutment Platform Diameter (in mm): 3.434 (3.5), 4.399 (4.5), 5.644 (5.7)	indications. The dental implant system diameter was updated to be consistent with the implant manufacturer platform diameter information. The implant body diameters are 3.5 mm, 4.0 mm, 5.0 mm and 6.0 mm, which correspond to the implant manufacturer's designation as follows: 3.5 = 3.5; 4.0 = 4.5; and 5.0/6.0 = 5.7. The special note was removed altogether for the following reasons: - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the Contraindications section of the Instructions for Use.
K070833	The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis Abutment for Astra Implant is compatible with Astra's OsseoSpeed™ 3.5(S) mm, 4.0(S) mm Internal Hex Implants. Please note: This device may be used in an early load	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). Removed the statement around "The prosthesis [crown] can be cemented retained to the abutment". This was removed as this is redundant since crowns are always cemented to an abutment.

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.	restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: Dentsply Sirona Implant System: OsseoSpeed/OsseoSpeed TX Implant Diameter (in mm): 3.5, 4.0 (Aqua) Abutment Platform Diameter (in mm): 2.866 (Aqua)	Added the abutment platform diameter information to be consistent with the more recent Atlantis Abutment clearances. Added Healing Abutment, Conus Abutment, and Crown Abutment indications. The special note was removed altogether for the following reasons: - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the Contraindications section of the Instructions for Use.
K062197	The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). Removed the statement around “The

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	The Atlantis Abutment for 3i Certain MicroMini Implant is compatible with 3i Osseotite NT® Certain and Parallel Walled Implants both with 3.25 mm diameters. Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant fixture.	Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: Biomet 3i Implant System: Certain, Certain Prevail Implant Diameter (in mm): 3.25, 3.4 Abutment Platform Diameter (in mm): 3.404	prosthesis [crown] can be cemented retained to the abutment". This was removed as this is redundant since crowns are always cemented to an abutment. Added the abutment platform diameter information to be consistent with the more recent Atlantis Abutment clearances. Biomet 3i implant platform of 3.25 corresponds to the 3.4 implant body size. Therefore, implants with designation 3.4, 3.25, or 3/4 correspond to the same implant size and therefore are compatible with the same Atlantis Abutment. The 3i Certain MicroMini Implant naming convention is no longer used by the implant manufacturer. Reference to the implant system has been updated to indicate 3i Certain and Certain Prevail implant system. Added Healing Abutment, Conus Abutment, and Crown Abutment indications. The special note was removed altogether for the following reasons: - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
			Contraindications section of the Instructions for Use.
K062069	The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. The Atlantis Abutment for 3i MicroMini Implant is compatible with the 3i: Osseotite NT® Certain and Parallel Walled Implants both with 3.25mm diameter; Nobel Biocare: Mk Ill 3.3m, Threaded IlL Series 3.3mm, IIL Immediate Impression 3.25mm, Cylindrical BL Series 325mm; BioHorizons: Maestro™ 3.5mm; Lifecore: Self-tapping 3.75mm, Threaded 3.3mm, Cylinder 3.4mm, Titanium 3.3mm; Sterugold: Implamed Hex Screw 3.3mm, 3.75mm, 4.0mm and 5.0mm, Hex Cylinder 3.3mm; Innova: Endopore® External 3.5mm and Entegram T External 3.25mm. Please note: This device may be used in an early load situation, but is dependent on the specific implant system and protocol used by the dental professional. Highly angled abutments (i.e. 30 degrees) on implants with diameters less than 4 mm are intended for the anterior region of the mouth and are not intended for the posterior region due to limited strength of the implant.	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing	This Atlantis Abutment is not available as "Atlantis Abutment Milling". Since the Indications for Use are generic for all proposed Atlantis Abutments in Titanium subject of this submission, the Atlantis Abutment Milling is part of the indications. The user will use the compatibility chart to confirm which abutments are available for design in 3Shape (Atlantis Abutment Milling). Removed the statement around "The prosthesis [crown] can be cemented retained to the abutment". This was removed as this is redundant since crowns are always cemented to an abutment. Added the abutment platform diameter information to be consistent with the more recent Atlantis Abutment clearances. Many of the implant systems originally cleared are discontinued. The compatibilities that remain active and included in the proposed Indications for Use are: • BioHorizons Maestro (which was listed in the K062069 indications as "Maestro™ 3.5mm") • Osseotite Tapered and Osseotite Parallel Walled (which was listed in the K062069 indications as "Osseotite NT Certain and Parallel Walled Implants both

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		Abutment to the endosseous implant. Implant Manufacturer: BioHorizons Implant System: Maestro Implant Diameter (in mm): 3.5 Abutment Platform Diameter (in mm): 3.708 Implant Manufacturer: Biomet 3i Implant System: Osseotite Tapered and Osseotite Parallel Walled Implant Diameter (in mm): 3.25 Abutment Platform Diameter (in mm): 4.056 Implant Manufacturer: Nobel Biocare Implant System: Branemark System (NP) Implant Diameter (in mm): 3.3 Abutment Platform Diameter (in mm): 3.476	with 3.25mm diameter") • Branemark (which was listed in the indications as "MK III 3.3mm") The special note was removed altogether for the following reasons: - The language regarding surgical technique (early loading protocol) is more appropriate for the implant system indications and has therefore been removed from the abutment indications. - The highly angled abutment limitations were moved to the Contraindications section of the Instructions for Use. Added Healing Abutment, Conus Abutment, and Crown Abutment indications. This abutment is not offered as a Healing Abutment. All Atlantis Abutments in Titanium share the same indications and Instructions for Use. The user will refer to the compatibility chart to confirm which abutments are available with which implant system.
K051652	The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant.	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). Removed the statement around "The prosthesis [crown] can be cemented

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: Dentsply Sirona Implant System: OsseoSpeed/OsseoSpeed TX Implant Diameter (in mm): 4.5, 5.0 (Lilac), 4.0 (Blue - Previous) Abutment Platform Diameter (in mm): 3.865 (Lilac), 3.368 (Blue - Previous)	retained to the abutment". This was removed as this is redundant since crowns are always cemented to an abutment. Added Healing Abutment, Conus Abutment, and Crown Abutment indications. Specified the compatible implant system, implant diameter, and abutment platform diameter to be consistent with the more recent Atlantis Abutment clearances.
K051011	The Atlantis Abutment is intended for use as an accessory to an endosseous implant to support a prosthetic device in a partially or completely	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic	Added Atlantis Abutment Milling to the Atlantis Abutment indications. Software validation is included in the

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
	edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be cement retained to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant.	device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: Biomet 3i Implant System: Certain: 4, 5, 6; Certain Prevail: 4, 5; Certain XP: 5, 6	submission to demonstrate that the same design limitations exist between the internal CAD software and the 3Shape software (K151455). Removed the statement around "The prosthesis [crown] can be cemented retained to the abutment". This was removed as this is redundant since crowns are always cemented to an abutment. Added Healing Abutment, Conus Abutment, and Crown Abutment indications. Specified the compatible implant system, implant diameter, and abutment platform diameter to be consistent with the more recent Atlantis Abutment clearances.

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		Implant Diameter (in mm): 4, 5, 6 Abutment Platform Diameter (in mm): 4.012 (4), 4.942 (5), 5.951 (6)	
K981858	The Atlantis Abutment is used to connect an implanted fixture to a restoration	The Atlantis Abutment and Atlantis Abutment Milling are intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The Atlantis Abutment screw is intended to secure the Atlantis Abutment to the endosseous implant. Atlantis Crown Abutment The Atlantis Crown Abutment is intended for use with an endosseous implant to function as a substructure that also serves as the final restoration, in a partially or completely edentulous patient. The Atlantis Abutment screw is intended to secure the Atlantis Crown Abutment to the endosseous implant. Atlantis Conus Abutment The Atlantis Conus Abutment is intended for use with an endosseous implant to support a prosthetic device in partially or completely edentulous patients. It is intended for use to support a removable multiple tooth prosthesis, in the mandible or maxilla. The prosthesis is an attachment- retained by friction fit to the abutment. The Atlantis Abutment screw is intended to secure the Atlantis Conus Abutment to the endosseous implant. Atlantis Healing Abutment The Atlantis Healing Abutment is intended for use with an endosseous implant for temporary use during soft tissue healing after one-stage or	Originally cleared indications are very generic. Complete rewrite of indications based on historical changes made to the Atlantis Abutments. This Atlantis Abutment is not available as "Atlantis Abutment Milling". Since the Indications for Use are generic for all proposed Atlantis Abutments in Titanium subject of this submission, the Atlantis Abutment Milling is part of the indications. The user will use the compatibility chart to confirm which abutments are available for design in 3Shape (Atlantis Abutment Milling). Added Healing Abutment, Conus Abutment, and Crown Abutment indications. This abutment is not offered as a Healing Abutment. All Atlantis Abutments in Titanium share the same indications and Instructions for Use. The user will refer to the compatibility chart to confirm which abutments are available with which implant system. Specified the compatible implant system, implant diameter, and abutment platform diameter to be consistent with the more recent Atlantis Abutment clearances.

510(k)	Predicate/Reference Device Indications for Use	Proposed Device Indications for Use	Discussion
		two-stage surgeries. The Atlantis Abutment screw is intended to secure the Atlantis Healing Abutment to the endosseous implant. Implant Manufacturer: BioHorizons Implant System: Maestro Implant Diameter: 4.0, 5.0 mm Abutment Platform Diameter: 4.242, 5.258 mm Implant Manufacturer: Biomet 3i Implant System: Osseotite Tapered and Osseotite Parallel Walled Implant Diameter: 3.75, 4.0, 5.0, 6.0 mm Abutment Platform Diameter: 4.056 (3.75, 4.0), 4.978 (5.0), 5.985 (6.0) Implant Manufacturer: NobelBiocare Implant System: Branemark System (RP, WP) Implant Diameter (in mm): 3.75, 4.0 (RP), 5.0, 5.5 (WP) Abutment Platform Diameter (in mm): 4.069 (RP), 5.033 (WP)	The implant system is referred to as "3i Standard threaded" in K981858 and is now referred to as "Osseotite" and "Osseotite XP". K981858 referred to the implant system as "Branemark RP" and "Branemark WP" which is consistent with the current naming convention. K981858 referred to the BioHorizons implant as Maestro which is consistent with the current naming convention.

6. Technological Comparison:

The primary purpose of the Bundled Traditional 510(k) premarket notification is to modify the labeling of the Atlantis® Abutments in Titanium to update the safety in an MR environment to indicate MR Conditional. The Abutments will be changed from MR Not Evaluated to MR Conditional. The labeling change reflects the requirements in the FDA guidance document, "Testing and Labeling Devices for Safety in the Magnetic Resonance (MR) Environment" and ensures that the clinician has the necessary information to communicate to the patient regarding the MR Safety of the proposed devices.

In addition to the MR Conditional labeling changes, internally documented changes and proposed modifications are included in the submission.

Angulated Screw Access (ASA)

Dentsply Sirona added the Angulated Screw Access (ASA) feature to some Atlantis® Abutments, as reviewed in reference device K151439, Atlantis® Suprastructures. The angulated screw access allows the clinician to access the screw access channel from the lingual side, which facilitates the installation procedure of the abutment.

Healing, Conus and Crown Abutment offering

Dentsply Sirona expanded the abutment offering to include Healing Abutments, Conus Abutments, and Crown Abutments that were not originally cleared with some Atlantis® Abutments. This offering is already cleared for the Atlantis® Abutment for MIS Conical Connection Implants in predicate device, K193529. The additional abutments (Healing, Conus, and Crown) are within the design envelope of the corresponding cleared Atlantis® Abutment implant system compatibilities and have the same mating geometry to the implant, which have been tested per ISO 14801 in respective original clearances.

Screw and abutment diameter modifications

Minor modification was made to some of the abutment screws since the original clearance of the Atlantis® Abutments in Titanium. These changes were made to standardize dimensions across the various custom abutment screws to simplify the procurement and quality control process. Upon review, the changes to the screws did not cause an interference with the internal geometry of the abutment and the modified screws are considered as safe and effective as the predicate device and reference device screws.

Limited to two implant system compatibilities (reference devices K073258 and K051652), the abutment diameter was slightly modified. Compatibility analysis was performed and the results indicate that the modifications do not result in a new worst-case for fatigue testing. Fatigue testing submitted in the original submissions remains valid.

Additional Compatibility

Added compatibility of existing Atlantis® Abutments in Titanium (K081666, K070833, K051652) with the Osseospeed TX implant system (K101732). The OsseoSpeed TX implant system has the same internal geometry as the OsseoSpeed Implant System (K080396, K053384, K041492) and therefore the Atlantis® Abutments in Titanium for OsseoSpeed/OsseoSpeed TX are compatible with both implant systems.

Atlantis Abutment Milling (Design in 3Shape)

Some Atlantis® Abutments (predicate device, K193529, and reference devices K151039,

K161030, K081666, K073258, K070833, K062197, K051652, K051011) can be designed by the user via 3Shape (3Shape Abutment Designer Software, K151455). After the abutment is designed by the lab, the abutment is manufactured by Dentsply Sirona. This proposed workflow is also referred to as Atlantis® Abutment Milling in this submission.

The design limitations that are locked in the 3Shape abutment library are the same design limitations as those in the internal DS CAD system called Virtual Abutment Design (VAD). To ensure that the same design limitations/constraints present in the 3Shape Atlantis® Abutment library match those in the internal CAD system, and that the design parameters cannot be exceeded, validation was performed. The software validation confirms that the additional option of using the 3Shape design module for design of Atlantis® Abutments does not raise new questions of safety and performance as it was confirmed that the locked design library for Atlantis® Abutments in 3Shape has the same design limitations as those built into the internal VAD software.

An overall comparison of the technological characteristics of the proposed modified Atlantis® Abutments in Titanium to the predicate device (K193529) and reference devices K161030, K151039, K081666, K073258, K070833, K062197, K062069, K051652, K051011, K981858) is provided in the Comparison Tables below.

Table 6.1 Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for MIS V3 and C1 implants and predicate device, Atlantis® Abutment in Titanium for MIS V3 and C1 implants (K193529)

Item	Modified Atlantis® Abutment in Titanium for MIS implants V3 and C1	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Same
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same
Restoration	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø2.765, 2.76, 3.16, 4.01 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Same
Compatible Implant diameter	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same
Compatible Implant System	MIS V3 (K163349), MIS C1 (K172505)	MIS V3 (K163349), MIS C1 (K172505)	Same
Connection	Internal Conical Connection	Internal Conical Connection	Same
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment	15 mm	15 mm	Same

Item	Modified Atlantis® Abutment in Titanium for MIS implants V3 and C1	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
height			
Maximum abutment width from implant axis	6 mm	6.5 mm	Different, however in K193529, the tested abutment maximum width from the implant axis was below 6.0 mm.
Minimum abutment width from implant axis	1.3525 mm	1.65 mm	Different, however in K193529, the worst-case abutment that was tested was within the minimum abutment width from the implant axis.
Minimum abutment post height	4 mm	4 mm	Same
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Same
Material: Screw	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Different due to additional ASA option.
Screw access angulation	Straight or angled up to 20°	Straight	Different due to additional ASA option.
Screw drive feature	Hex Hexalobular	Hex	Different due to the hexalobular screw drive feature for Atlantis ASA screwdriver.
MR Safety	MR Conditional	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.2: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for Conelog implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for Conelog implants (K161030)

Item	Modified Atlantis® Abutment in Titanium for Conelog implants	Reference device Atlantis® Abutment in Titanium for Conelog implants (K161030)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Same
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same offering as the predicate device. The same design envelope applies to all Atlantis Healing Abutments in Titanium.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø2.80, 3.00, 3.80 mm	Ø2.80, 3.00, 3.80 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Same as reference device
Compatible Implant Diameter	Ø 3.3, 3.8, 4.3, 5.0 mm	Ø 3.3, 3.8, 4.3, 5.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device
Compatible Implant System	Conelog Screw-Line Implant 3.3 Conelog Screw-Line Implant 3.8/4.3 Conelog Screw-Line Implant 5.0 (K113779)	Conelog implant system (K113779)	MIS V3 (K163349), MIS C1 (K172505)	Same. No change. Table now specifies the individual compatible Conelog implants instead of the system as a whole.
Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	6.5 mm	6.5 mm	Different, however in K161030, the tested abutment maximum width from the implant axis was below 6.0 mm.
Minimum abutment width from implant axis	1.3525 mm	1.65 mm	1.65 mm	Different, however in K161030, the worst-case abutment that was tested was within the minimum abutment width from

Item	Modified Atlantis® Abutment in Titanium for Conelog implants	Reference device Atlantis® Abutment in Titanium for Conelog implants (K161030)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
				the implant axis.
Minimum abutment post height	4 mm	4 mm	4 mm	Same
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw	Straight screw	Straight screw	Same
Screw access angulation	Straight	Straight	Straight	Same
Screw drive feature	Hex	Hex	Hex	Same
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.3: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for Nobel Active 3.0 implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for Nobel Active 3.0 implants (K151039)

Item	Modified Atlantis® Abutment in Titanium for Nobel Active 3.0 implants	Reference device Atlantis® Abutment in Titanium for Nobel Active 3.0 implants (K151039)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Note: Atlantis Conus Abutment with friction fit is not currently marketed for this implant	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained Friction Fit	Same
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Healing Abutment Note: Atlantis Conus Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Offering is covered by predicate device. The additional offering is within the same design envelope as the reference device.

Item	Modified Atlantis® Abutment in Titanium for Nobel Active 3.0 implants	Reference device Atlantis® Abutment in Titanium for Nobel Active 3.0 implants (K151039)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
	is not currently marketed for this implant			
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø2.461 mm	Ø2.461 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Same as reference device
Compatible Implant Diameter	3.0 mm	3.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device
Compatible Implant System	Nobel Biocare Active Implant 3.0 (K102436)	Nobel Biocare Active Implant 3.0 (K102436)	MIS V3 (K163349), MIS C1 (K172505)	Same as reference device
Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	6.5 mm	6.5 mm	Different, however in K151039, the tested abutment maximum width from the implant axis was below 6.0 mm.
Minimum abutment width from implant axis	1.3525 mm	1.65 mm	1.65 mm	Different, however in K151039, the worst-case abutment that was tested was within the minimum abutment width from the implant axis.
Minimum abutment post height	4 mm	4 mm	4 mm	Same
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw Angulated screw – access hole on	Straight screw	Straight screw	Different due to additional ASA option.

Item	Modified Atlantis® Abutment in Titanium for Nobel Active 3.0 implants	Reference device Atlantis® Abutment in Titanium for Nobel Active 3.0 implants (K151039)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
	the lingual side			
Screw access angulation	Straight or angled up to 30°	Straight	Straight	Different due to additional ASA option. The ASA screw access channel ranges from 0 to 30°.
Screw drive feature	Unigrip Hexalobular	Unigrip	Hex	Different due to the hexalobular screw drive feature for Atlantis ASA screwdriver.
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.4: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for OsseoSpeed 3.0 implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for AstraTech OsseoSpeed 3.0 implants (K081666)

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed 3.0 implants	Reference device Atlantis® Abutment in Titanium for OsseoSpeed 3.0 implants (K081666)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as reference device
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Offering is covered by predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø2.330 mm	Ø2.330 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Same as reference device
Compatible Implant Diameter	Ø 3.0 mm	Ø 3.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed 3.0 implants	Reference device Atlantis® Abutment in Titanium for OsseoSpeed 3.0 implants (K081666)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Compatible Implant System	OsseoSpeed 3.0 - Yellow OsseoSpeed TX 3.0 - Yellow Note: OsseoSpeed and OsseoSpeed TX have the same connection. (K080396, K101732)	Osseospeed 3.0 implant (K080396)	MIS V3 (K163349), MIS C1 (K172505)	The connection of the Dentsply Sirona OsseoSpeed and OsseoSpeed TX implants are identical and therefore the Atlantis Abutments in Titanium cleared in K081666 are compatible with both Dentsply Sirona OsseoSpeed (K080396) and OsseoSpeed TX (K101732) implant systems.
Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6.5 mm	Different but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.65 mm	Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed 3.0 implants	Reference device Atlantis® Abutment in Titanium for OsseoSpeed 3.0 implants (K081666)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Screw type	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw	Different due to additional ASA option.
Screw access angulation	Straight or angled up to 30°	Straight	Straight	Different due to additional ASA option. The ASA screw access channel ranges from 0 to 30°.
Screw drive feature	Hexalobular Hex	Hex	Hex	Different due to the hexalobular screw drive feature for Atlantis ASA screwdriver.
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.5: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for BioHorizons implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for BioHorizons implants (K073258)

Item	Modified Atlantis® Abutment in Titanium for BioHorizons implants	Reference device Atlantis® Abutment in Titanium for BioHorizons implants (K073258)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction-fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as the predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø3.434, 4.399, 5.644 mm	Ø3.536, 4.514, 5.720 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Similar. Minor changes in abutment diameter. Verification and validation activities in design controls confirm continued compatibility and applicability of existing fatigue

Item	Modified Atlantis® Abutment in Titanium for BioHorizons implants	Reference device Atlantis® Abutment in Titanium for BioHorizons implants (K073258)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
				testing.
Compatible Implant Diameter	3.5, 4.5, 5.7 mm	3.5, 4.5, 5.7 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device
Compatible Implant System	BioHorizons Internal 3.5 BioHorizons Internal 4.5 BioHorizons Internal 5.7 (K042429)	BioHorizons Prodigy System (K042429)	MIS V3 (K163349), MIS C1 (K172505)	Same as reference device Compatible with the same implant system. Branding name change only.
Connection	Internal Hex, Tapered Internal	Internal Hex, Tapered Internal	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6.5 mm	Different but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.65 mm	Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Same
Material:	Titanium alloy	Titanium alloy	Titanium alloy	Same

Item	Modified Atlantis® Abutment in Titanium for BioHorizons implants	Reference device Atlantis® Abutment in Titanium for BioHorizons implants (K073258)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Screw				
Screw type	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw	Different due to additional ASA option.
Screw access angulation	Straight or angled up to 20°	Straight	Straight	Different due to additional ASA option. The ASA screw access channel ranges from 0 to 20°.
Screw drive feature	Hexalobular Hex	Hex	Hex	Different due to the hexalobular screw drive feature for Atlantis ASA screwdriver.
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.6: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for OsseoSpeed 3.5 and 4.0 mm implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for OsseoSpeed 3.5 and 4.0 mm implants (K070833)

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed implants 3.5 and 4.0	Reference device Atlantis® Abutment in Titanium for OsseoSpeed implants 3.5 and 4.0 (K070833)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction-fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as the predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø2.866 mm	Ø2.866 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Same as reference device

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed implants 3.5 and 4.0	Reference device Atlantis® Abutment in Titanium for OsseoSpeed implants 3.5 and 4.0 (K070833)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Compatible Implant Diameter	3.5, 4.0 mm	3.5, 4.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device
Compatible Implant System	OsseoSpeed 3.5/4.0 – Aqua OsseoSpeed TX 3.5/4.0 - Aqua (K053384, K101732) Note: Microthread OsseoSpeed and Osseospeed/OsseoSpeed TX have the same connection.	OsseoSpeed implants (formerly AstraTech implants) (K053384, K024111)	MIS V3 (K163349), MIS C1 (K172505)	The connection of the Dentsply Sirona OsseoSpeed and OsseoSpeed TX implants are identical and therefore the Atlantis Abutments in Titanium cleared in K070833 are compatible with both Dentsply Sirona OsseoSpeed (K053384) and OsseoSpeed TX (K101732) implant systems. Microthread implants branding changed to OsseoSpeed. Implants cleared in K024111 are discontinued.
Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6.5 mm	Different but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.65 mm	Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment	4 mm	Not specified	4 mm	Added minimum abutment post height to be consistent with

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed implants 3.5 and 4.0	Reference device Atlantis® Abutment in Titanium for OsseoSpeed implants 3.5 and 4.0 (K070833)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
post height				more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw Angulated screw – access hole on the lingual side	Straight screw	Straight screw	Different due to additional ASA option.
Screw access angulation	Straight or angled up to 30°	Straight	Straight	Different due to additional ASA option. The ASA screw access channel ranges from 0 to 30°.
Screw drive feature	Hexalobular Hex	Hex	Hex	Different due to the hexalobular screw drive feature for Atlantis ASA screwdriver.
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.7: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for Biomet 3i Certain implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for Biomet 3i Certain implants (K062197)

Item	Modified Atlantis® Abutment in Titanium for Biomet 3i Certain implants	Reference device Atlantis® Abutment in Titanium for Biomet 3i Certain implants (K062197)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction-fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.

Item	Modified Atlantis® Abutment in Titanium for Biomet 3i Certain implants	Reference device Atlantis® Abutment in Titanium for Biomet 3i Certain implants (K062197)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as the predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø3.404 mm	Ø3.404 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Same as reference device
Compatible Implant Diameter	3.25, 3.4 mm	3.25, 3.4 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device
Compatible Implant System	Biomet 3i Certain 3.25 Biomet 3i Certain 4/3 Biomet 3i Certain Prevail 3/4/3 (3.4), 4/3 (K051461)	Biomet 3i Certain implants (K041235)	MIS V3 (K163349), MIS C1 (K172505)	Same. Compatible with the same implant system. Branding name change only. Note: K062197 referenced the incorrect implant system, an external implant system (K041235). The correct implant system is K051461.
Connection	Internal Hexagon Connection	Internal Hexagon Connection	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6.5 mm	Different but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.65 mm	Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the

Item	Modified Atlantis® Abutment in Titanium for Biomet 3i Certain implants	Reference device Atlantis® Abutment in Titanium for Biomet 3i Certain implants (K062197)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
				same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw	Straight screw	Straight screw	Same
Screw access angulation	Straight	Straight	Straight	Same
Screw drive feature	Hex	Hex	Hex	Same
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.8: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for Biomet, Nobel Biocare and BioHorizons implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for Biomet, Nobel Biocare and BioHorizons implants (K062069)

Item	Modified Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare and BioHorizons implants	Reference device Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare and BioHorizons implants (K062069)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction-fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Offering is covered by predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Biomet: Ø 4.056 mm Nobel: Ø 3.476 mm BioHorizons: 3.708 mm	Biomet: Ø 3.25 mm implant diameter Nobel: Ø 3.3 mm implant diameter BioHorizons: 3.5 mm implant diameter	Ø2.765, 2.76, 3.16, 4.01 mm	Same as reference device. The submission did not specify the abutment platform diameter and instead referred to compatible implant diameters for all other implant system compatibilities cleared.
Compatible Implant Diameter	Biomet: 3.25 Nobel: 3.3 mm BioHorizons: 3.5 mm	Biomet: 3.25 mm Nobel: 3.3 mm BioHorizons: 3.5 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device
Compatible Implant System	3i Osseotite Tapered and Parallel Walled (K014235, K031475, K041402) Nobel Biocare Branemark System NP 3.3 (K050705) BioHorizons 3.5 (K010458)	3i Osseotite NT Certain and 3i Osseotite Certain Parallel walled Implant (K014235, K031475, K041402) Nobel Biocare 3.3 mm implants (K050705) BioHorizons 3.5 (K010458)	MIS V3 (K163349), MIS C1 (K172505)	Compatible with same implant systems. Branding name change only.
Connection	External Hexagon Connection	External Hexagon Connection	Internal Conical Connection	Same as reference device
Abutment	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same

Item	Modified Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare and BioHorizons implants	Reference device Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare and BioHorizons implants (K062069)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
angulation				
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6.5 mm	Different but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.65 mm	Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Titanium alloy, Gold Shaded Titanium	Same
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw	Straight screw	Straight screw	Same
Screw access angulation	Straight	Straight	Straight	Same
Screw drive feature	Unigrip Hex	Unigrip Hex	Hex	Same as reference device
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.9: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for Osseospeed/Osseospeed TX implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for Osseospeed implants (K051652)

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed implants	Reference device Atlantis® Abutment in Titanium for OsseoSpeed implants (K051652)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction-fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as the predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø 3.368, 3.865 mm	Ø 3.463 for Ø 4.0 mm For the larger size, the submission did not specify the abutment platform diameter but the compatible implant diameter of Ø 4.5, 5.0	Ø2.765, 2.76, 3.16, 4.01 mm	Minor changes in abutment diameter. Verification and validation activities in design controls confirm continued compatibility and applicability of existing fatigue testing.
Compatible Implant Diameter	Ø 4.0, 4.5, 5.0 mm	Ø 4.0, 4.5, 5.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device
Compatible Implant System	OsseoSpeed 4.0 Blue (Previous) (K041492) OsseoSpeed/OsseoSpeed TX 4.5, 5.0 - Lilac Note: Microthread OsseoSpeed and Osseospeed/OsseoSpeed TX have the same connection. (K053384, K101732)	Microthread OsseoSpeed 4.0, 4.5, 5.0 (Compatible implant system is not specified in submission but referred to as Astra's Microthread ST 4.0, 4.5, and 5.0 mm, which corresponds to K041492, K053384)	MIS V3 (K163349), MIS C1 (K172505)	The connection of the Dentsply Sirona OsseoSpeed and OsseoSpeed TX implants are identical and therefore the Atlantis Abutments in Titanium cleared in K051652 are compatible with both Dentsply Sirona OsseoSpeed (K041492, K053384) and OsseoSpeed TX (K101732) implant systems.
Connection	Internal Conical Connection	Internal Conical Connection	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed implants	Reference device Atlantis® Abutment in Titanium for OsseoSpeed implants (K051652)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Maximum abutment width from implant axis	6 mm	5.5 mm	6.5 mm	Different but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.65 mm	Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy	Titanium alloy, Gold Shaded Titanium	Same as predicate device. Gold-shaded titanium abutments (TiN abutments) have been reviewed by the Agency during the predicate device submission as well as in earlier submissions. This corresponds to Titanium with a titanium nitride layer applied using PVD (Physical Vapor Deposition) to create a gold shade for a more esthetic outcome.
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw Angulated screw	Straight screw	Straight screw	Different due to additional ASA option.
Screw access	Straight or angled up to 30°	Straight	Straight	Different due to additional ASA option.

Item	Modified Atlantis® Abutment in Titanium for OsseoSpeed implants	Reference device Atlantis® Abutment in Titanium for OsseoSpeed implants (K051652)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
angulation				The ASA screw access channel ranges from 0 to 30°.
Screw drive feature	Hexalobular Hex	Hex	Hex	Different due to the hexalobular screw drive feature for Atlantis ASA screwdriver.
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update

Table 6.10: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for 3i Certain implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for 3i Certain implants (K051011)

Item	Modified Atlantis® Abutment in Titanium for 3i Certain implants	Reference device Atlantis® Abutment in Titanium for 3i Certain implants (K051011)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Same as the predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Ø 4.012, 4.942, 5.951 mm	Ø 4.012, 4.942, 5.951 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Same as reference device
Compatible Implant Diameter	Ø 4.0, 5.0, 6.0 mm	Ø 4.0, 5.0, 6.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm C1: Ø3.3, 3.75, 4.2, 5.0 mm	Same as reference device
Compatible Implant System	Biomet 3i Certain 4.0, 5.0, 6.0, 5/4 Biomet 3i Certain Prevail 4/5/4, 5/6/5, 5/4, 6/5 Biomet Certain XP 4/5, 5/6	3i Certain 3.75W, 4, 4/3, 5, 4/5, 4/5/4, 5/4, 5/6, 5/6/5, 6, 6/5 (K031475)	MIS V3 (K163349), MIS C1 (K172505)	Compatible with same implant system. Branding name change only. Note: Some abutments have been discontinued.

Item	Modified Atlantis® Abutment in Titanium for 3i Certain implants	Reference device Atlantis® Abutment in Titanium for 3i Certain implants (K051011)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
	(K031475)			
Connection	Internal hexagon connection	Internal hexagon connection	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6.5 mm	Different but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.65 mm	Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Added minimum abutment post height to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy	Titanium alloy, Gold Shaded Titanium	Same as predicate device. Gold-shaded titanium abutments (TiN abutments) have been reviewed by the Agency during the predicate device submission as well as in earlier submissions. This corresponds to Titanium with a titanium nitride layer applied using PVD (Physical Vapor Deposition) to create a gold shade for a more esthetic outcome.
Material:	Titanium alloy	Titanium alloy	Titanium alloy	Same

Item	Modified Atlantis® Abutment in Titanium for 3i Certain implants	Reference device Atlantis® Abutment in Titanium for 3i Certain implants (K051011)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Screw				
Screw type	Straight screw	Straight screw	Straight screw	Same
Screw access angulation	Straight	Straight	Straight	Same
Screw drive feature	Hex	Hex	Hex	Same
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

Table 6.11: Comparison of the technological characteristics between proposed modified Atlantis® Abutment in Titanium for Biomet, Nobel Biocare, and BioHorizons implants, predicate device, Atlantis® Abutment in Titanium (K193529), and reference device Atlantis® Abutment in Titanium for Biomet, Nobel Biocare, and BioHorizons implants (K981858)

Item	Modified Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare, and BioHorizons implants	Reference device Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare, and BioHorizons implants (K981858)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Prosthesis attachment	Screw-retained Cement-retained Friction Fit	Screw-retained Cement-retained	Screw-retained Cement-retained Friction Fit	Same as predicate device. Added Friction-fit with the introduction of the Conus Abutment.
Abutments	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment	Atlantis Abutment	Atlantis Abutment Atlantis Crown Abutment Atlantis Conus Abutment Atlantis Healing Abutment	Offering is covered by predicate device. The additional offering is within the same design envelope as the reference device.
Restoration	Single or Multi-unit	Single or Multi-unit	Single or Multi-unit	Same
Abutment platform diameter	Biomet: 4.056, 4.978, 5.985 mm Nobel: 4.069, 5.033 mm BioHorizons: 4.242, 5.258 mm	4, 5, 6, 7 mm	Ø2.765, 2.76, 3.16, 4.01 mm	Same range The reference device submission specified a range of abutment diameters of 4.0 through 7.0 mm.
Implant	Biomet: 3.75, 4.0, 5.0, 6.0 mm	Biomet: 3.75, 4.0, 5.0, 6.0 mm	V3: Ø3.3, 3.9, 4.3, 5.0 mm	Same as reference device

Item	Modified Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare, and BioHorizons implants	Reference device Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare, and BioHorizons implants (K981858)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
Platform Diameter	Nobel: 3.75, 4.0, 5.0, 5.5 mm BioHorizons: 4.0, 5.0 mm	Nobel: 3.75, 4.0, 5.0, 5.5 mm BioHorizons: 4.0, 5.0 mm	C1: Ø3.3, 3.75, 4.2, 5.0 mm	
Compatible Implant System	Biomet 3i Osseotite 3.75, 4.0, 5.0, 6.0 Biomet Osseotite XP 4/5, 5/6 (K983347) Branemark RP 3.75 and 4.0 Branemark WP 5.0 and 5.5 (K974828, K022562) BioHorizons External 4.0 and 5.0 (K972313)	3i Standard Threaded Ø 3.75, 4.0, 6.0 mm 3i Standard Cylinder Ø 4.0, 4.25 mm (currently the 4/5, 5/6) Branemark RP 3.75, 4.0, and and 5.0 Branemark WP 5.0 and 5.5 BioHorizons External 4.0 and 5.0 Note: the submission did not specify the compatible implant system 510(k) clearances.	MIS V3 (K163349), MIS C1 (K172505)	Same as reference device with some sizes discontinued.
Connection	External Hexagon Connection	External Hexagon Connection	Internal Conical Connection	Same as reference device
Abutment angulation	Straight, Up to 30°	Straight, Up to 30°	Straight, Up to 30°	Same
Maximum abutment height	15 mm	15 mm	15 mm	Same
Maximum abutment width from implant axis	6 mm	5.5 mm	6.5 mm	Different but still within the 6 mm maximum limit.
Minimum abutment width from implant axis	1.3525 mm	Not specified	1.65 mm	Added minimum abutment width from implant axis to be consistent with more recently cleared Atlantis Abutments. All Atlantis Abutments share the same design envelope.
Minimum abutment post height	4 mm	Not specified	4 mm	Added minimum abutment post height to be consistent with more recently cleared Atlantis

Item	Modified Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare, and BioHorizons implants	Reference device Atlantis® Abutment in Titanium for Biomet 3i, Nobel Biocare, and BioHorizons implants (K981858)	Predicate device, Atlantis® Abutment in Titanium for MIS implants V3 and C1 (K193529)	Discussion
				Abutments. All Atlantis Abutments share the same design envelope.
Material: Abutment	Titanium alloy, Gold Shaded Titanium	Titanium alloy	Titanium alloy, Gold Shaded Titanium	Same as predicate device. Gold-shaded titanium abutments (TiN abutments) have been reviewed by the Agency during the predicate device submission as well as in earlier submissions. This corresponds to Titanium with a titanium nitride layer applied using PVD (Physical Vapor Deposition) to create a gold shade for a more esthetic outcome.
Material: Screw	Titanium alloy	Titanium alloy	Titanium alloy	Same
Screw type	Straight screw	Straight screw	Straight screw	Same
Screw access angulation	Straight	Straight	Straight	Same
Screw drive feature	Hex Unigrip	Hex Unigrip	Hex	Same as reference device
MR Safety	MR Conditional	MR Not Evaluated	MR Not Evaluated	Different. Testing included in reference device (K221094) supports labeling update.

7. Non-Clinical Tests Summary and Conclusion:

To support the labeling change from MR Not Evaluated or no MR information on the labeling to MR Conditional labeling, testing included in reference device, OmniTaper EV Dental Implants, DS Implants with EV connection (K221094) is included by reference. The proposed Atlantis® Abutments in Titanium meet the requirements of:

- ASTM F2052-21, Standard test method for measurement of magnetically induced displacement force on medical devices in the magnetic resonance environment
- ASTM F2213-17, Standard test method for measurement of magnetically induced torque on medical devices in magnetic resonance environment
- ASTM F2119-07 (2013), Standard test method for evaluation of MR image artifacts from passive implants,
- ASTM F2503-20, Standard practice for marking medical devices and other items for safety in the magnetic resonance environment,
- FDA guidance document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" dated October 10, 2023

Biocompatibility assessment was performed to evaluate the biocompatibility profile of the Atlantis® Abutments in Titanium according to the following standards:

- ISO 10993-1:2018, Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- Cytotoxicity testing was performed according to ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

Reprocessing testing was performed to validate the proposed drying time for steam sterilization. The sterilization drying time validation followed the FDA guidance document titled "Reprocessing Medical Device in Health Care Settings: Validation Methods and Labeling".

- Sterilization and drying time validation was performed according to:
  - ANSI/AAMI/ISO 17665-1:2006/(R)2013, Annex D, Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
  - ANSI/AAMI/ISO 14937:2009/(R)2013, Annex D (Approach 3), Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation, and routing control of a sterilization process
  - AAMI TIR12:2020, Designing, testing and labeling medical devices intended for processing by health care facilities: A guide for manufacturers
  - ANSI/AAMI/ISO TIR17665-2:2009, Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO ANSI/AAMI/ISO 17665-1.

CAD/CAM Software Validation & Verification Testing for Atlantis® Abutment Milling:
Software validation was performed to show that the Atlantis® abutment design limitations were implemented within the 510(k) cleared abutment design software (3Shape Abutment Designer Software, K151455).

The internally documented and proposed modifications to the Atlantis® Abutments in Titanium and screws did not affect the performance of the devices and therefore no new fatigue testing is

included in this submission. The abutments continue to meet the requirements of ISO 14801:2016, Dentistry – Implants – Dynamic loading test for endosseous dental implants and FDA Guidance, Root-form Endosseous Dental Implants and Endosseous Dental Abutments – Class II Special Controls Guidance Document.

The testing described above confirmed that the proposed Atlantis® Abutments in Titanium are substantially equivalent to the predicate device (K193529) and reference devices (K161030, K151039, K081666, K073258, K070833, K062197, K062069, K051652, K051011, K981858) and do not raise new questions regarding safety and effectiveness.

8. Clinical Tests Summary and Conclusion:
   Not applicable. There are no clinical tests submitted, referenced, or relied on in the 510(k) for a determination of substantial equivalence.

9. Conclusion Regarding Substantial Equivalence:
   The proposed Atlantis® Abutments in Titanium have the same intended use and similar indications as compared to the predicate device Atlantis® Conical Connection Abutment for MIS Implant (K193529). The abutments labeling is modified to conform to FDA guidance document "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" and testing performed on the worst-case Dentsply Sirona implant products validates the labeling change to indicate MR Conditional.

   In addition to the MR labeling change which is the main purpose of this submission, additional internally documented changes and proposed changes were reviewed against the original clearance of the predicate (K193529) and reference devices (K161030, K151039, K081666, K073258, K070833, K062197, K062069, K051652, K051011, K981858) and the changes do not raise new questions about safety and effectiveness. Test data is included in this premarket notification to verify and validate the changes to the proposed devices and the results support a conclusion of substantial equivalence.