August 6, 2026

Nobel Biocare AB
Bernice Jim
Head of RA Implant Systems
Vastra Hamngatan 1
Goteborg, Vastra SE 411 17
SWEDEN

Re: K253999
Trade/Device Name: Universal Base ASC Engaging; Universal Base ASC Non-Engaging; Universal Base MUA ASC; Temporary Abutment Engaging and Non-Engaging; Omnigrip Clinical Screw Titanium; Omnigrip Prosthetic Screw; Healing Abutment Conical Connection
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA, PNP
Dated: July 6, 2026
Received: July 6, 2026

Dear Bernice Jim:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253999

Please provide the device trade name(s).

Universal Base ASC Engaging;
Universal Base ASC Non-Engaging;
Universal Base MUA ASC;
Temporary Abutment Engaging and Non-Engaging;
Healing Abutment Conical Connection;
Omnigrip Clinical Screw Titanium;
Omnigrip Prosthetic Screw

Please provide your Indications for Use below.

Universal Bases ASC Engaging:
Universal Bases ASC Engaging are indicated to support the placement of single unit, screw retained prosthetic restorations in the maxilla or mandible.
The Universal Base consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.
The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories.

Universal Bases ASC Non-Engaging:
Universal Bases ASC Non-Engaging are indicated to support the placement of multiple unit, screw retained prosthetic restorations in the maxilla or mandible.
The Universal Base Non-Engaging consists of multiple parts. Specifically, the titanium base and multi-unit mesostructure components make up a multi-piece abutment.
The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories.

Universal Bases MUA ASC:
Universal Base MUA ASC are indicated to support the placement of multiple unit, screw retained prosthetic restorations in the maxilla or mandible.
The Universal Base MUA consists of three major parts, specifically the Multi-unit abutment, the Universal Base MUA and the mesostructure components make up a multi-piece abutment.
The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories.

Temporary Abutment Engaging and Non-Engaging:
Temporary Abutments Engaging CC are indicated for use with single unit screw- retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.
Temporary Abutment Non-Engaging CC are indicated for use with multiple unit screw-retained temporary dental prosthesis placed on endosseous dental implant in the maxilla and mandible, for up to 180 days, for implants with less than 14° overall divergences to allow path of insertion.

Omnigrip Clinical Screw Titanium:
Clinical Screws are indicated for use to secure a dental abutment or framework to a dental implant in the

maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

Omnigrip Prosthetic Screw:
Prosthetic screws are indicated for use to secure a dental abutment or framework to a dental abutment or base in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

Healing Abutment Conical Connection:
The Healing Abutments Conical Connection are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for one single tooth to full arch denture procedures.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

1 – 510(k) Summary

1.1 Submitter Information

Submitter:	Nobel Biocare AB Vastra Hamngatan 1 Goteborg 411 17 Sweden
Submitted By:	Nobel Biocare Services AG Balz-Zimmerman-Strasse 7 8302 Kloten Switzerland
Contact Person:	Bernice Jim, PhD
E-Mail: Telephone Number:	regulatory.affairs.nb@envistaco.com +41 43 211 42 00
Prepared By:	Nicole Fuchs, MLaw
Oversight (Manager):	Valeria Barbarito, MSc
Date Prepared	August 6th 2026

1.2 Device Name No. 1

Proprietary name:	Universal Base ASC Engaging
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Primary Product Code:	NHA
Secondary Product Code:	PNP

1.3 Device Name No. 2

Proprietary name:	Universal Base ASC Non-Engaging
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Primary Product Code:	NHA
Secondary Product Code:	PNP

1.4 Device Name No. 3

Proprietary name:	Universal Base MUA ASC
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Primary Product Code:	NHA
Secondary Product Code:	PNP

1.5 Device Name No. 4

Proprietary name:	Temporary Abutment Engaging and Non-Engaging
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Product Code:	NHA

1.6 Device Name No. 5

Proprietary name:	Healing Abutment Conical Connection
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Product Code:	NHA

1.7 Device Name No. 6

Proprietary name:	Omnigrip Clinical Screw Titanium
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment Screw
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Product Code:	NHA

1.8 Device Name No. 7

Proprietary name:	Omnigrip Prosthetic Screw
Manufacturer:	Nobel Biocare AB
Common Name:	Dental Abutment Screw
Classification Name:	Endosseous Dental Implant Abutment
Regulation Number:	21 CFR 872.3630
Device Class:	II
Product Code:	NHA

1.9 Predicate Device

Primary Predicate

K200040	Universal Base Conical Connection, Nobel Biocare

Reference Devices

1	K233208	NobelProcera Titanium Abutment ASC, Nobel Biocare
2	K240982	DESS® Dental Smart Solutions, Terrats Medical SL
3	K211109	N1 Base Xeal + Universal Abutment N1 Base Tri Bridge, Nobel Biocare
4	K201860	Elos Accurate Hybrid Base (Universal Base non-engaging Elos), Elos
5	K211109	Temporary Abutment Nobel Biocare N1™ TCC, Nobel Biocare
6	K161435	Temporary Snap Abutment (Engaging and Non-Engaging), Nobel Biocare
7	K102436, K133731	Healing Abutment Conical Connection, Nobel Biocare
8	K233208	Omnigrip Clinical Screw Titanium, Nobel Biocare
9	K211109	Clinical Screw Multi-unit Abut Nobel Biocare N1 TCC, Nobel Biocare
10	K220048	Prosthetic Screw NobelProcera Zr Nobel Biocare N1 Base, Nobel Biocare
11	K202452	Prosthetic Screw MUA Omnigrip Mini, Nobel Biocare

1.10 Device Description Summary

The subject device Universal Base ASC is composed of three device lines:

- Universal Base ASC (including three devices: Universal Base ASC Engaging, Universal Base ASC Non-Engaging, Universal Base MUA ASC)
- Temporary Abutments (including two devices: Temporary Abutments Engaging and Non-Engaging, Healing Abutment Conical Connection)
- Screws (including two devices: Omnigrip Clinical Screw Titanium and Omnigrip Prosthetic Screw).

Universal Base ASC and Temporary Abutment device lines are premanufactured dental implant abutments which can either be connected directly to a Nobel Biocare Conical Connection implant or to a Multi-unit Abutment to support the placement of a screw-retained dental prosthesis. The Universal Base ASC device line integrates a digital workflow using a dental CAD software and is milled from zirconia. Both Universal Base ASC and Temporary Abutment device lines are available in the platform sizes NP, RP and WP and are intended for use as an aid in prosthetic rehabilitation to restore chewing function and esthetic appearance.

The Universal Base ASC and Temporary Abutments device lines are connected to the implant with a clinical screw. The Universal Base ASC features an angulated screw channel which can be defined by the end user in an angulation (to the implant's axis) between 0° and 25°. The clinical screw features the Omnigrip Interface which allows tightening up to 25°.

The Universal Base ASC, Temporary Abutments and Screw device lines are composed of titanium vanadium alloy Ti6Al4V ELI (ISO 5832-3, ASTM F136), the surface of the abutments is provided with full anodization and the Clinical Screws are provided with, without and with partial DLC coating.

1.10.1 Device Description Summary

The tables below outline the material compositions and relevant size ranges (e.g. diameter, length, angulation, etc.) for all models of each device component for the proposed Universal Base ASC Engaging, Universal Base ASC Non-Engaging, Universal Base MUA ASC, Temporary Abutments Engaging and Non-Engaging, Healing Abutments Conical Connection, Omnigrip Screw Clinical Titanium, and Omnigrip Prosthetic Screw devices.

Design specifications

Universal Base ASC Engaging and Non-Engaging:

Parameter	Specification
Maximum Mesostructure Angulation	20°
Maximum Angulation of screw channel	25°
Min Wall Thickness	0.5 mm
Max Wall Thickness	Based on the blank dimensions available for Vita YZ® ST Multicolor by Vita
Min Abutment Post Height	4 mm
Max Abutment Post Height	Based on the blank dimensions available for Vita YZ® ST Multicolor by Vita
Min Gingiva Height	1 mm (given by the standardized abutment shape of the Universal Base Engaging and Non-Engaging)
Max Gingiva Height	3.5 mm (given by the standardized abutment shape of the Universal Base Engaging and Non-Engaging)
Compatible cement	Multilink Hybrid by Ivoclar Vivadent (K130436)

Universal Base ASC MUA:

Parameter	Specification
Maximum Mesostructure Angulation	20°
Maximum Angulation of screw channel	25°
Min Wall Thickness	0.5 mm
Max Wall Thickness	Based on the blank dimensions available for Vita YZ® ST Multicolor by Vita
Min Abutment Post Height	5 mm
Max Abutment Post Height	Based on the blank dimensions available for Vita YZ® ST Multicolor by Vita
Min Gingiva Heigh	1.5 mm (given by the standardized shape of the Multi-Unit Abutment)
Compatible cement	Multilink Hybrid by Ivoclar Vivadent (K130436)

Physical Characteristics

Universal Base ASC Engaging and Non-Engaging:

Platform	Collar Height (mm)
NP	1, 1.5, 2.5, 3.5
RP	1, 1.5, 2.5, 3.5
WP	1, 1.5, 2.5

Temporary Abutments:

Device	Platform	Diameter (mm)	Gingival Height (mm)	Height (mm)
Temporary Abutments Conical Connection Engaging and Non-Engaging	NP	4.1	1.5, 2.5, 3.5	11
	RP	4.3, 4.8	1.5, 2.5, 3.5	11
	WP	4.8	1.5, 2.5	11
Healing Abutments Conical Connection	3.0	3.3, 4	3, 5	-
	NP	4, 5	3, 5	-
	RP	4, 5, 6	3, 5	-
	WP	5, 6.5	3, 5	-

Screws:

Device	Platform	Shaft Diameter (mm)	Total Length (mm)
Long Omnigrip Screw Clinical	NP	2.3	9.475
	RP/WP	2.52	9.45
MUA Prosthetic Screw	NP/RP/WP	2.3	4.125

Material compositions

Device Line	Body Material Description	Surface Treatment Description	Mesostructure and Cement
Universal Base ASC	Titanium-6 Aluminum-4 Vanadium alloy: 90% Ti, 6% Al, 4% V (ASTM F136 and ISO 5832-3)	full dip surface anodization	Mesostructure: VITA YZ ST (K180703) Vita Zahnfabrik H. Rauter GmbH Multilink Hybrid Abutment Cement: Ivoclar Vivadent AG (K130436)
Temporary Abutments	Titanium-6 Aluminum-4 Vanadium alloy: 90% Ti, 6% Al, 4% V (ASTM F136 and ISO 5832-3)	full dip surface anodization	N/A
Screws	Titanium-6 Aluminum-4 Vanadium alloy: 90% Ti, 6% Al, 4% V (ASTM F136 and ISO 5832-3)	Diamond Like Carbon (DLC) coating	N/A

1.11 Intended Use/Indication for Use

Universal Bases ASC Engaging:

Universal Bases ASC Engaging are indicated to support the placement of single unit, screw retained prosthetic restorations in the maxilla or mandible.

The Universal Base consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment.

The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories.

Universal Bases ASC Non-Engaging:

Universal Bases ASC Non-Engaging are indicated to support the placement of multiple unit, screw retained prosthetic restorations in the maxilla or mandible.

The Universal Base Non-Engaging consists of multiple parts. Specifically, the titanium base and multi-unit mesostructure components make up a multi-piece abutment.

The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories.

Universal Bases MUA ASC:

Universal Base MUA ASC are indicated to support the placement of multiple unit, screw retained prosthetic restorations in the maxilla or mandible.

The Universal Base MUA consists of three major parts, specifically the Multi-unit abutment, the Universal Base MUA and the mesostructure components make up a multi-piece abutment.

The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories.

Temporary Abutment Engaging and Non-Engaging:

Temporary Abutments Engaging CC are indicated for use with single unit screw-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.

Temporary Abutment Non-Engaging CC are indicated for use with multiple unit screw-retained temporary dental prosthesis placed on endosseous dental implant in the maxilla and mandible, for up to 180 days.

Omnigrip Clinical Screw Titanium:

Clinical Screws are indicated for use to secure a dental abutment or framework to a dental implant in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

Omnigrip Prosthetic Screw:

Prosthetic screws are indicated for use to secure a dental abutment or framework to a dental abutment or base in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.

Healing Abutment Conical Connection:

The Healing Abutments Conical Connection are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for one single tooth to full arch denture procedures.

1.12 Indications for Use Comparison

The Intended Use statement and Indications for Use statement are the same, differing only in the choice of words.

1.13 Technological Comparison

1.13.1 Universal Base ASC

Table 1: Universal Base ASC Engaging, Predicate and Reference Device Summary

Characteristic	**Subject Device**	**Predicate Device**	**Reference Device # 1**	**Reference Device # 2**	
	Universal Base ASC Engaging	**Universal Base CC**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	**Comparison:**
		K200040	**K233208**	**K240982**	
Manufacturer	Nobel Biocare	Nobel Biocare	Nobel Biocare	**Terrats Medical SL**	
Intended Use					
Pictorial representation				n/a	n/a
Product Classification	Class II	Class II	Class II	Class II	Same as Predicate Device
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same as Predicate Device
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same as Predicate Device
Product Code, primary	NHA	NHA	NHA	NHA	Same as Predicate Device
Product Code, secondary	PNP	PNP	n/a	n/a	Same as Predicate Device
Review Panel	Dental	Dental	Dental	Dental	Same as Predicate Device

Characteristic	Subject Device	Predicate Device	Reference Device # 1	Reference Device # 2	
	Universal Base ASC Engaging	**Universal Base CC**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	**Comparison:**
Intended Use	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis	The Universal Base Conical Connection are attached to Nobel Biocare dental implants and are intended to support a crown.	Nobel Biocare's NobelProcera®/Procera® Abutment Titanium/Zirconia is a customized dental abutment. The abutment attaches directly to the endosseous dental implant with a clinical screw and provides a platform for restoration	*DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.* *All digitally designed custom abutments for use with DESS Bases or Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories*	Same intended use, differing only in the choice of words
Indications for Use	Universal Bases Conical Connection Engaging are indicated to support the placement of single unit, screw retained prosthetic restorations in the maxilla or mandible. The Universal Base consists of two major parts. Specifically, the titanium base and mesostructured components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories.	The Universal Base Conical Connection is a premanufactured prosthetic component directly connected to endosseous dental implants and is intended for use as an aid in prosthetic rehabilitation. The Universal Base Conical Connection consists of two major parts. Specifically, the titanium base and mesostructure components make up a two-piece abutment. The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	Nobel Biocare's NobelProcera/Procera Abutment Titanium/Zirconia is indicated for the treatment of partially edentulous patients requiring prosthetic Devices and/or endosseous implants to restore chewing function.		Same indications use, differing only in the choice of words
Clinical setting	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	Same as Predicate Device
Primary User Population	Dental healthcare professionals	Dental healthcare professionals	Dental healthcare professionals	Dental healthcare professionals	Same as Predicate Device
Patient Population	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Same as Predicate Device
Anatomical Site	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Same as Predicate Device
Technological Characteristics					
Device Dimensions/ Design Specifications					

Characteristic	Subject Device	Predicate Device	Reference Device # 1	Reference Device # 2	
	Universal Base ASC Engaging	**Universal Base CC**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	**Comparison:**
Minimum wall thickness Mesostructure:	0.5 mm	0.8 mm	0.4 mm	0.4 mm	Similar as Reference Device #1
Minimum platform diameter					
NP	Ø 4.1	Ø 4.775	Ø 3.13	For NobelActive/ NobelReplace/ NobelParallel Conical Connection: 3.5 – 5.5	Similar to Predicate Device
RP	Ø 4.3	Ø 4.775	Ø 3.46		Similar to Predicate Device
WP	Ø 4.8	Ø 6.515	Ø 4.486		Similar to Predicate Device
Minimum gingiva height:	1 mm	0.275 mm	0.3 mm	0.5 mm	Similar to Predicate Device
Minimum abutment post height:	4mm (above gingival collar height)	4mm	4mm	4.0 mm	Same as Predicate Device
Screw Channel	ASC (0-25°)	Straight	ASC (0-25°)	Straight	same as Reference Device #1
Abutment Shape	Standardized	Standardized	Patient Specific	Patient Specific	Same as Predicate Device
Platform compatibility	Narrow Platform (NP)	Narrow Platform (NP)	Narrow Platform (NP)	Narrow Platform (NP)	Same as Predicate Device
	Regular Platform (RP)	Regular Platform (RP)	Regular Platform (RP)	Regular Platform (RP)	Same as Predicate Device
	Wide Platform (WP)	Wide Platform (WP)	Wide Platform (WP)	Wide Platform (WP)	Same as Predicate Device
Connection interface	conical connection	conical connection	conical connection	conical connection	Same as Predicate Device
Attachment method to implant	Screw retained	Screw retained	Screw retained	Screw retained	Same as Predicate Device
Mesostructure attachment method	Cement retained	Cement retained	Cement retained	Cement retained	Same as Predicate Device
Restoration type	Single-unit	Single-unit	Single-unit and multi-unit	Single-unit and multi-unit	Same as Predicate Device
Design features	2-piece abutment Abutment premanufactured Single unit	2-piece abutment Abutment premanufactured Single unit	Pre-manufactured implant-interface connection, customizable cylindrical abutment body	2-piece abutment Abutment	Same as Predicate Device
Principle of operation/ Mechanism of action	Mechanical screw connection	Mechanical screw connection	Mechanical screw connection	Not part of publicly available 510k summary.	Same as Predicate Device
Maximum Mesostructure angulation	20°	20°	N/A	30°	Same as Predicate Device

Characteristic	Subject Device	Predicate Device	Reference Device # 1	Reference Device # 2	
	Universal Base ASC Engaging	**Universal Base CC**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	**Comparison:**
Base Material	Titanium aluminum vanadium alloy	Titanium aluminum vanadium alloy	Titanium aluminum vanadium alloy	Titanium aluminum vanadium alloy	Same as Predicate Device
	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Same as Predicate Device
Mesostructure/Crown Material	VITA YZ ST (K180703) Vita Zahnfabrik H. Rauter GmbH	Vita Enamic IS (K153645) Vita Zahnfabrik H. Rauter GmbH	n/a	VITA YZ ST (K180703) Vita Zahnfabrik H. Rauter GmbH	Same as Reference Device #2 materials
Adhesive Material	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	n/a	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Same as Predicate Device
Surface treatment	anodized	none	anodized	Not part of publicly available 510k summary.	Same as Reference Device #1
Biocompatibility	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-5, -12	Same as Predicate Device
Tissue contact	Permanent contact with bone and soft tissue	Permanent contact with bone and soft tissue	Permanent contact with bone and soft tissue	Not part of publicly available 510k summary.	Same as Predicate Device
Digital design workflow	Creation of patient scan at dental practice	Creation of patient scan at dental practice	n/a	Not part of publicly available 510k summary.	Same as Predicate Device
	Export of scan to design software	Export of scan to design software	n/a		Same as Predicate Device
	Design of customization of abutment according to design restrictions	Design of customization of abutment according to design restrictions	n/a		Same as Predicate Device
Equipment for digital design workflow					
Scanner	3Shape intra oral scanner Trios (3Shape A/S) or other scanners with accuracy equal or higher.	3Shape intra oral scanner Trios (3Shape A/S)	n/a	3Shape intra oral scanner Trios (3Shape A/S) 3Shape desktop scanner D900 Dental Lab Scanner	Same as Predicate Device
Design Workflow	CAD	CAD	Wax-up or CAD.	CAD	Same as Predicate Device
CAD design software:	3Shape (K151455)	3Shape (K151455)	3Shape (K151455)	3Shape (K151455)	Same as Predicate Device
			DTX Studio Lab (K181932)		
	ExoCAD (K193352)	ExoCAD (K193352)[1]	ExoCAD (K193352)	ExoCAD (K193352)	

[1] Nobel Biocare has added the ExoCAD library and categorized the change as non-significant, the addition the libraries to 510k cleared software does not change the safety or effectiveness of the Device.

Characteristic	Subject Device	Predicate Device	Reference Device # 1	Reference Device # 2	
	Universal Base ASC Engaging	**Universal Base CC**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	**Comparison:**
Manufacturing Workflow	Milling unit CORiTEC by imes-icore	Milling unit CORiTEC by imes-icore	Customization milled at Device manufactuer.	Milling unit VHF R5 by vhf camfacture AG with DentalCAM and DentalCNC 7 software	Same as Predicate Device
Sterility	Provided non-sterile – terminally sterilized via autoclave prior to implantation	Provided non-sterile – terminally sterilized via autoclave prior to implantation	Provided non-sterile – terminally sterilized via autoclave prior to implantation	Provided non-sterile	Same as Predicate Device
Single Use or Reusable	Single use	Single use	Single use	Single use	Same as Predicate Device
MRI compatibility	MR Conditional	MR Conditional	MR Conditional	MR Conditional	Same as Predicate Device
	(cleared in K212125)	(cleared in K212125)	(cleared in K212125)		Same as Predicate Device
Packaging					
Packaging	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.[2]	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Procera packaging	Not part of publicly available 510k summary.	Same as Predicate Device
Co-Packing	co-packed with screw	co-packed with screw	Screw	Not part of publicly available 510k summary.	Same as Predicate Device
Fatigue Testing	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Not part of publicly available 510k summary.	Same as Predicate Device

[2] Packaging system reviewed and cleared with K243834

Table 2: Universal Base ASC Non-Engaging Predicate and Reference Device Summary

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #4	Reference Device #1	Reference Device #2	Comparison:
	Universal Base Non-Engaging	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**Elos Accurate Hybrid Base (Universal Base non-engaging Elos)**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
		K211109	**K201860**	**K233208**	**K240982**	
Manufacturer	Nobel Biocare	Nobel Biocare	**Elos**	Nobel Biocare	**Terrats Medical SL**	
Intended Use						
Pictorial representation					n/a	n/a
Product Classification	Class II	Class II	Class II	Class II	Class II	Same as Predicate Device (Reference Device #3)
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same as Predicate Device (Reference Device #3)
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same as Predicate Device (Reference Device #3)
Product Code, primary	NHA	NHA	NHA	NHA	NHA	Same as Predicate Device (Reference Device #3)
Product Code, secondary	PNP	PNP	PNP	N/A	N/A	Same as Predicate Device (Reference Device #3)
Review Panel	Dental	Dental	Dental	Dental	Dental	Same as Predicate Device (Reference Device #3)
Intended Use	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis	Intended to be connected to an endosseous dental implant to support the	Support of a prothesis to restore chewing function	IFU3010: Nobel Biocare's NobelProcera®/Procera® Abutment Titanium/Zirconia is a customized dental abutment. The abutment	*DESS Dental Smart Solutions abutments are intended to be used in*	Same intended use, differing only in the choice of words

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #4	Reference Device #1	Reference Device #2	Comparison:
	Universal Base Non-Engaging	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**Elos Accurate Hybrid Base (Universal Base non-engaging Elos)**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
		placement of a dental prosthesis.		attaches directly to the endosseous dental implant with a clinical screw and provides a platform for restoration	*conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.* *All digitally designed custom abutments for use with DESS Bases or Pre-milled Blanks are to be sent to a Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories*	
Indications for Use	Universal Bases Conical Connection Non-Engaging are indicated to support the placement of multiple unit, screw retained prosthetic restorations in the maxilla or mandible. The Universal Base Non-Engaging consists of multiple parts. Specifically, the titanium base and multi-unit mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories	The Universal Abutment Nobel Biocare N1™ Base consist of three major parts. Specifically, the N1 Base Xeal, the Universal Abutment N1 Base, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. <u>Nobel Biocare N1™ Base Xeal™</u> The Nobel Biocare N1™ Base Xeal™ is indicated for use in the maxilla or mandible for supporting tooth replacements to restore chewing function. It is indicated	The Elos Accurate® Hybrid Base™ is intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Hybrid Base™ is used as an interface between a dental implant and a zirconia superstructure and will be attached to the implant using a prosthetic screw and attached to the zirconia superstructure by cementing. The Elos Accurate® Hybrid Base™ is compatible with the implant systems listed in table 1: The zirconia superstructures for use with the Elos Accurate® Hybrid Base™ are only intended to be designed and manufactured according to digital dentistry workflow. The workflow system integrates multiple components of the digital dentistry workflow: scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories.	Nobel Biocare's NobelProcera/Procera Abutment Titanium/Zirconia is indicated for the treatment of partially edentulous patients requiring prosthetic Devices and/or endosseous implants to restore chewing function.		Same indications for use, differing only in the choice of words

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #4	Reference Device #1	Reference Device #2	Comparison:
	Universal Base Non-Engaging	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**Elos Accurate Hybrid Base (Universal Base non-engaging Elos)**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
		for single unit restorations and multiple unit restorations up to 6 units with less than 20° divergence to allow path of insertion. <u>Universal Abutment Nobel Biocare N1™ Base Tri Bridge</u> The Universal Abutment Nobel Biocare N1™ Base Tri Bridge is indicated to support the placement of multiple unit of up to 6 units, screw-retained prosthetic restorations in the maxilla or mandible for implants with less than 20° overall divergences to allow path of insertion.				
Clinical setting	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	N/A	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	Same as Predicate Device (Reference Device #3)
Primary User Population	Dental healthcare professionals	Dental healthcare professionals	N/A	Dental healthcare professionals	Dental healthcare professionals	Same as Predicate Device (Reference Device #3)
Patient Population	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	N/A	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Same as Predicate Device (Reference Device #3)
Anatomical Site	Oral cavity	Oral cavity	N/A	Oral cavity	Oral cavity	Same as Predicate Device (Reference Device #3)
Technological Characteristics						
Device Dimensions/ Design Specifications						

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #4	Reference Device #1	Reference Device #2	Comparison:
	Universal Base Non-Engaging	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**Elos Accurate Hybrid Base (Universal Base non-engaging Elos)**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
Minimum wall thickness:	0.5 mm	Circular: 0.5 mm Margin: 0.35 mm	0.5 mm	0.42 mm	0.4 mm	Same as Predicate Device (Reference Device #3)
Minimum platform diameter						
NP	Ø 4.1mm	Ø 4.8 mm	3.0 - 6.0 mm	Ø 3.13 mm	For NobelActive/ NobelReplace/ NobelParallel Conical Connection: 3.5 – 5.5	Similar to Predicate Device (Reference Device #3)
RP	Ø 4.3mm	Ø 5.0 mm		Ø 3.46 mm		
WP	Ø 4.8mm	n/a		Ø 4.486 mm		
Minimum gingiva height:	1 mm	n/a	0.5 mm	0.3 mm	0.5 mm	Similar as Predicated Device (Reference Device #3)
Minimum abutment post height:	4mm (above gingival collar height)	5.2 mm	4mm	4mm	4.0 mm	In range of Predicate Device (Reference Device #3) and Reference Device #4
Screw Channel	ASC (0-25°)	straight	straight	ASC (0-25°)	Straight	Same as Reference Device #1
Abutment Shape	Standardized	Standardized	Standardized	Patient Specific	Patient Specific	Same as Predicate Device (Reference Device #3)
Platform compatibility	Narrow Platform (NP)	Narrow Platform (NP)	Narrow Platform (NP)	Narrow Platform (NP)	Narrow Platform (NP)	Same as Predicate Device (Reference Device #3)
	Regular Platform (RP)	Regular Platform (RP)	Regular Platform (RP)	Regular Platform (RP)	Regular Platform (RP)	Same as Predicate Device (Reference Device #3)
	Wide Platform (WP)	N/A	Wide Platform (WP)	Wide Platform (WP)	Wide Platform (WP)	Same as Predicate Device (Reference Device #3)
Connection interface	conical connection	trioval conical connection	conical connection	conical connection	conical connection	Same as Reference Device #4
Attachment method to implant	Screw retained	Screw retained	Screw retained	Screw retained	Screw retained	Same as Predicate Device (Reference Device #3)
Mesostructure attachment method	Cement retained	Cement retained	Cement retained	Cement retained	Cement retained	Same as Predicate Device (Reference Device #3)
Restoration type	multi-unit	multi-unit	Single-unit and multi-unit	Single-unit and multi-unit	Single-unit and multi-unit	Same as Predicate Device (Reference Device #3)
Design features	2-piece abutment Abutment, premanufactured, Multi-unit	3-piece abutment. Abutment, premanufactured, Multi-unit	2 piece - zirconia bonded to hybrid base mounted on to the implant and fixe with a screw	Pre-manufactured implant-interface connection, customizable cylindrical abutment body	2-piece abutment Abutment	Same as Reference Device #4
Principle of operation/ Mechanism of action	Mechanical screw connection	Mechanical screw connection	Mechanical screw connection	Mechanical screw connection	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #4	Reference Device #1	Reference Device #2	Comparison:
	Universal Base Non-Engaging	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**Elos Accurate Hybrid Base (Universal Base non-engaging Elos)**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
Maximum Mesostructure angulation	20°	20°	20°	30°	30°	Same as Predicate Device (Reference Device #3)
Base Material	Titanium aluminium vanadium alloy	Titanium aluminium vanadium alloy	Titanium aluminium vanadium alloy	Titanium aluminium vanadium alloy	Titanium aluminium vanadium alloy	Same as Predicate Device (Reference Device #3)
	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Ti6Al4V ELI (ISO 5832-3, ASTM F136)	Same as Predicate Device (Reference Device #3)
Mesostructure Material	VITA YZ ST (K180703) Vita Zahnfabrik H. Rauter GmbH	Zirconia Nacera Pearl (K143071) Doceram Medical Ceramics GmbH	3M Lava Plus Zirconia (K011394)	n/a	VITA YZ ST (K180703) Vita Zahnfabrik H. Rauter GmbH	Same as Reference Device #2
Adhesive Material	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	n/a	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Same as Predicate Device (Reference Device #3)
Surface treatment	anodized	anodized	n/a	anodized	Not part of publicly available 510k summary	Same as Reference Device #1
Biocompatibility	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-5	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-5, -12	Same as Predicate Device (Reference Device #3)
Tissue contact	Permanent contact with bone and soft tissue	Permanent contact with bone and soft tissue	n/a	Permanent contact with bone and soft tissue	Not part of publicly available 510k summary	Same as Predicate Device (Reference Device #3)
Digital design workflow	Creation of patient scan at dental practice	Creation of patient scan at dental practice	n/a	Customization milled at Device manufacturer	Not part of publicly available 510k summary	Same as Predicate Device (Reference Device #3)
	Export of scan to design software	Export of scan to design software				Same as Predicate Device (Reference Device #3)
	Design of customization of abutment according to design restrictions	Design of customization of abutment according to design restrictions				Same as Predicate Device (Reference Device #3)
Equipment for digital design workflow						
Scanner	3Shape intra oral scanner Trios (3Shape A/S) or other scanners with accuracy equal or higher	3Shape intra oral scanner Trios (3Shape A/S)	3Shape intra oral scanner Trios (3Shape A/S)	n/a	3Shape intra oral scanner Trios (3Shape A/S)	Same as Predicate Device (Reference Device #3)

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #4	Reference Device #1	Reference Device #2	Comparison:
	Universal Base Non-Engaging	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**Elos Accurate Hybrid Base (Universal Base non-engaging Elos)**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
					3Shape desktop scanner D900 Dental Lab Scanner	
Design Workflow	CAD	CAD	CAD	Wax-up or CAD.	CAD	Same as Predicate Device (Reference Device #3)
CAD design software	3Shape (K151455)	Design software: DTX Studio Design (K181932, where the implant libraries are automatically included in the software installer) or 3Shape Abutment Designer Software (K151455, where the implant libraries are obtained via the 3Shape server in the software).	Design software 3Shape Abutment Designer Software (K151455, where the implant libraries are obtained via the 3Shape server in the software).	3Shape (K151455), or DTX Studio Lab (K181932)	3Shape (K151455)	Same as Reference Device #2
	ExoCAD (K193352)			ExoCAD (K193352)	ExoCAD (K193352)	Same as Predicate Device (Reference Device #3)
Manufacturing Workflow	Milling unit CORiTEC by imes-icore	Milling unit - Indicated for Zirconia milling - Minimum 5 axis milling technology - Minimum 30.000 rpm spindle speed	Milling unit CORiTEC by imes-icore	Customization milled at Device manufactuer.	Milling unit VHF R5 by vhf camfacture AG with DentalCAM and DentalCNC 7 software	Same as Reference Device #4
Sterility	Provided non-sterile – terminally sterilized via autoclave prior to implantation	N1 Base Xeal: provided sterile – Gamma Radiation SAL 10^{-6} Universal Abutment N1 Base Bridge; Provided non-sterile – terminally sterilized via autoclave prior to implantation	n/a	Provided non-sterile – terminally sterilized via autoclave prior to implantation	Provided non-sterile	Same as Predicate Device (Reference Device #3)
Single Use or Reusable	Single use	Single use	Single use	Single use	Single use	Same as Predicate Device (Reference Device #3)
MRI compatibility	MR Conditional	MR Conditional	n/a	MR Conditional	MR Conditional	Same as Predicate Device (Reference Device #3)

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #4	Reference Device #1	Reference Device #2	Comparison:
	Universal Base Non-Engaging	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**Elos Accurate Hybrid Base (Universal Base non-engaging Elos)**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
	(cleared in K212125)	(cleared in K212125)	n/a	(cleared in K212125)	n/a	Same as Predicate Device (Reference Device #3)
Packaging						
Packaging	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	n/a	Procera packaging	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)
Co-Packing	co-packed with screw	co-packed with screw	n/a	co-packed with screw	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)
Fatigue Testing	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	n/a	Dynamic Fatigue Testing per ISO 14801	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)

Table 3: Universal Base MUA ASC Predicate and Reference Device Summary

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #1	Reference Device #2	Comparison:
	Multi-unit Abutment Conical Connection Xeal + Universal Base MUA	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
	Nobel Biocare	Nobel Biocare	Nobel Biocare	**K240982**	
Intended Use		**K211109**	**K233208**	**Terrats Medical SL**	
Pictorial representation				n/a	n/a
Product Classification	Class II	Class II	Class II	Class II	Same as Predicate Device (Reference Device #3)
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same as Predicate Device (Reference Device #3)
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same as Predicate Device (Reference Device #3)
Product Code, primary	NHA	NHA	NHA	NHA	Same as Predicate Device (Reference Device #3)
Product Code, secondary	PNP	PNP	N/A	N/A	Same as Predicate Device (Reference Device #3)
Review Panel	Dental	Dental	Dental	Dental	Same as Predicate Device (Reference Device #3)
Intended Use	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis.	IFU3010: Nobel Biocare's NobelProcera®/Procera® Abutment Titanium/Zirconia is a customized dental abutment. The abutment attaches directly to the endosseous dental implant with a clinical screw and provides a platform for restoration	*DESS Dental Smart Solutions abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for prosthetic restorations.* *All digitally designed custom abutments for use with DESS Bases or Pre-milled Blanks are to be sent to a*	Same intended use, differing only in the choice of words
Indications for Use	Universal Bases Conical Connection Non-Engaging and Universal Base MUA are indicated	The Universal Abutment Nobel Biocare N1™ Base consist of three major parts. Specifically, the N1 Base Xeal, the	Nobel Biocare's NobelProcera/Procera Abutment Titanium/Zirconia		Same indications use, differing only in the choice of words

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #1	Reference Device #2	Comparison:
	Multi-unit Abutment Conical Connection Xeal + Universal Base MUA	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
	to support the placement of multiple unit, screw retained prosthetic restorations in the maxilla or mandible. The Universal Base MUA consists of three major parts, specifically the Multi-unit abutment, the Universal Base MUA and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow: scan files from intra oral scanners, CAD software, CAM software, ceramic and ceramic-dominant material, milling machine and associated tooling and accessories	Universal Abutment N1 Base, and the mesostructure components make up a multi-piece abutment. The system integrates multiple components of the digital dentistry workflow scan files from Intra-Oral Scanners, CAD software, CAM software, ceramic material, milling machine and associated tooling and accessories. Nobel Biocare N1™ Base Xeal™ The Nobel Biocare N1™ Base Xeal™ is indicated for use in the maxilla or mandible for supporting tooth replacements to restore chewing function. It is indicated for single unit restorations and multiple unit restorations up to 6 units with less than 20° divergence to allow path of insertion. Universal Abutment Nobel Biocare N1™ Base Tri Bridge The Universal Abutment Nobel Biocare N1™ Base Tri Bridge is indicated to support the placement of multiple unit of up to 6 units, screw-retained prosthetic restorations in the maxilla or mandible for implants with less than 20° overall divergences to allow path of insertion.	is indicated for the treatment of partially edentulous patients requiring prosthetic Devices and/or endosseous implants to restore chewing function.	*Terrats Medical validated milling center for manufacture, or to be designed and manufactured according to the digital dentistry workflow. The digital dentistry workflow integrates multiple components: scan files from intra-oral and lab (desktop) scanners, CAD software, CAM software, ceramic material, milling machine, and associated tooling and accessories*	
Clinical setting	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	Same as Predicate Device (Reference Device #3)
Primary User Population	Dental healthcare professionals	Dental healthcare professionals	Dental healthcare professionals	Dental healthcare professionals	Same as Predicate Device (Reference Device #3)
Patient Population	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Same as Predicate Device (Reference Device #3)
Anatomical Site	Oral cavity	Oral cavity	Oral cavity	Oral cavity	Same as Predicate Device (Reference Device #3)
Technological Characteristics					

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #1	Reference Device #2	Comparison:
	Multi-unit Abutment Conical Connection Xeal + Universal Base MUA	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
Device Dimensions/ Design Specifications					
Minimum wall thickness	0.5 mm	Circular: 0.5 mm Margin: 0.35 mm	0.42 mm	0.4 mm	Same as Predicate Device (Reference Device #3)
Minimum platform diameter					
NP/RP/WP	NP/RP/WP Ø 5	NP Ø 4.8 RP Ø 5	Ø 3.13 - Ø 4.486	For NobelActive/ NobelReplace/ NobelParallel Conical Connection: 3.5 – 5.5	Same as Predicate Device (Reference Device #3)
Minimum gingival height	1.5 mm	1.5 mm	0.3 mm	0.5 mm	Same as Predicate Device (Reference Device #3)
Minimum abutment post height:	5mm (above gingival collar height)	5.2 mm	4mm	4.0 mm	Similar to Predicate Device (Reference Device #3) and Reference Device #1
Screw Channel	ASC (0-25°)	straight	ASC (0-25°)	Straight	Same as Reference Device #1
Abutment Shape	Standardized	Standardized	Patient Specific	Patient Specific	Same as Predicate Device (Reference Device #3)
Platform compatibility	Compatible with Nobel Biocare Conical Connection Multi-unit Abutment platforms NP, RP and WP	Narrow Platform (NP)	Narrow Platform (NP)	Narrow Platform (NP)	Same as Reference Device #1
		Regular Platform (RP)	Regular Platform (RP)	Regular Platform (RP)	
		n/a	Wide Platform (WP)	Wide Platform (WP)	
Connection interface	Multi-unit Abutment: conical connection Universal Base MUA: Multi-unit Abutment	Trioval conical connection	conical connection	conical connection	Same as Reference Device #1
Attachment method to implant	Screw retained	Screw retained	Screw retained	Screw retained	Same as Predicate Device (Reference Device #3)
Mesostructure attachment method	Cement retained	Cement retained	Cement retained	Cement retained	Same as Predicate Device (Reference Device #3)
Restoration type	Multi-unit	multi-unit	Single-unit and multi-unit	Single-unit and multi-unit	Same as Predicate Device (Reference Device #3)

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #1	Reference Device #2	Comparison:
	Multi-unit Abutment Conical Connection Xeal + Universal Base MUA	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
Design features	Multi-piece abutment Abutment premanufactured Single or Multi-unit	3-piece abutment. Abutment premanufactured Multi-unit	Pre-manufactured implant-interface connection, customizable cylindrical abutment body	2-piece abutment Abutment	Same as Predicate Device (Reference Device #3)
Principle of operation/ Mechanism of action	Mechanical screw connection	Mechanical screw connection	Mechanical screw connection	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)
Maximum Mesostructure angulation	20°	20°	30°	30°	Same as Predicate Device (Reference Device #3)
Material Base	Titanium aluminum vanadium alloy	Titanium aluminium vanadium alloy	Titanium aluminum vanadium alloy	Titanium aluminium vanadium alloy	Same as Predicate Device (Reference Device #3)
	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Same as Predicate Device (Reference Device #3)
Mesostructure/Crown Material	VITA YZ ST (K180703) Vita Zahnfabrik H. Rauter GmbH	Zirconia Nacera Pearl (K143071) Doceram Medical Ceramics GmbH	n/a	VITA YZ ST (K180703) Vita Zahnfabrik H. Rauter GmbH	Same as Reference Device #2
Adhesive Material	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Multilink Hybrid Abutment Cement Ivoclar Vivadent AG (K130436)	Same as Predicate Device (Reference Device #3)
Surface treatment	anodized	anodized	anodized	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)
Biocompatibility	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-5, -12	Same as Predicate Device (Reference Device #3)
Tissue contact	Permanent contact with bone and soft tissue	Permanent contact with bone and soft tissue	Permanent contact with bone and soft tissue	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)
Digital design workflow	Creation of patient scan at dental practice	Creation of patient scan at dental practice	Creation of patient scan at dental practice	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)
	Export of scan to design software	Export of scan to design software	Export of scan to design software		Same as Predicate Device (Reference Device #3)
	Design of customization of abutment according to design restrictions	Design of customization of abutment according to design restrictions	Design of customization of abutment according to design restrictions		Same as Predicate Device (Reference Device #3)
Equipment for digital design workflow					

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #1	Reference Device #2	Comparison:
	Multi-unit Abutment Conical Connection Xeal + Universal Base MUA	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
Scanner:	3Shape intra oral scanner Trios (3Shape A/S) or other scanners with accuracy equal or higher	3Shape intra oral scanner Trios (3Shape A/S)	n/a	3Shape intra oral scanner Trios (3Shape A/S) 3Shape desktop scanner D900 Dental Lab Scanner	Same as Predicate Device (Reference Device #3)
Design Workflow	CAD	CAD	Wax-up or CAD.	CAD	Same as Predicate Device (Reference Device #3)
CAD design software	3Shape (K151455)	Design software: DTX Studio Design (K181932, where the implant libraries are automatically included in the software installer) or 3Shape Abutment Designer Software (K151455, where the implant libraries are obtained via the 3Shape server in the software).	3Shape (K151455)	3Shape (K151455)	Same as Predicate Device (Reference Device #3)
			DTX Studio Lab (K181932)		
	ExoCAD (K193352)		ExoCAD (K193352)	ExoCAD (K193352)	Same as Reference Device #1
Manufacturing Workflow	Milling unit CORiTEC by imes-icore	Milling unit - Indicated for Zirconia milling - Minimum 5 axis milling technology - Minimum 30.000 rpm spindle speed	Customization milled at Device manufactuer.	Milling unit VHF R5 by vhf camfacture AG with DentalCAM and DentalCNC 7 software	Same as Predicate Device (Reference Device #3)
Sterility	Provided non-sterile – terminally sterilized via autoclave prior to implantation	N1 Base Xeal: provided sterile – Gamma Radiation SAL 10^{-6} Universal Abutment N1 Base Bridge; Provided non-sterile – terminally sterilized via autoclave prior to implantation	Provided non-sterile – terminally sterilized via autoclave prior to implantation	Provided non-sterile	Same as Reference Device #1
Single Use or Reusable	Single use	Single use	Single use	Single use	Same as Predicate Device (Reference Device #3)
MRI compatibility	MR Conditional	MR Conditional	MR Conditional	MR Conditional	Same as Predicate Device (Reference Device #3)
	(cleared in K212125)	(cleared in K212125)	(cleared in K212125)		Same as Predicate Device (Reference Device #3)
Packaging					
Packaging	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Procera packaging	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)
Co-Packing	co-packed with screw	co-packed with screw	Screw	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)

Characteristic	Subject Device	Predicate Device (Reference Device #3)	Reference Device #1	Reference Device #2	Comparison:
	Multi-unit Abutment Conical Connection Xeal + Universal Base MUA	**N1 Base Xeal + Universal Abutment N1 Base Tri Bridge**	**NobelProcera Titanium Abutment ASC**	**DESS Dental Smart Solutions**	
Fatigue Testing	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Dynamic Fatigue Testing per ISO 14801	Not part of publicly available 510k summary.	Same as Predicate Device (Reference Device #3)

The similarities between the Subject device line Universal Base ASC Engaging, Non-Engaging and MUA ASC and the Primary Predicate (and Reference Devices # 1, 2, 3 and 4) Device are as follows:

- The Intended Use statement and Indications for Use statement are the same, differing only in the choice of words
- Principle of operations, design features and workflow, attachment methods, device material, compatible devices are the same or similar for the Subject Devices and the Predicate Devices. Furthermore, all the Subject and Predicate Devices are non-sterile, single-use devices.
- Subject Device Lines and the Primary Predicate Devices are labelled MR Conditional

Details of the Differences Between the Subject and Predicate Device:

There are no significant differences between the Subject and predicate devices but there are minor differences as follows:

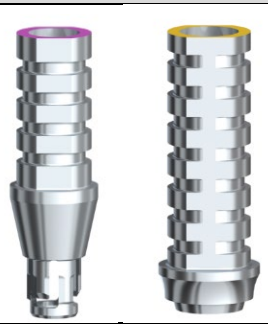
- The dimensions are different in the Subject and Predicate device but remain in the range of the Predicate Device and Reference Device.
- Compared to the Predicate Device, the Subject Device is provided with anodization, an angulated screw channel and connection interface, in addition the Subject Device can be used with a different in-lab milling unit then the Predicate.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the device line Universal Base ASC is deemed to be substantially equivalent to the Primary Predicate Device. The new devices do not introduce a fundamentally new scientific technology and the non-clinical tests demonstrate that the devices are substantially equivalent.

1.13.2 Temporary Abutments

Table 4: Temporary Abutment Engaging and Non-Engaging Predicate and Reference Device Summary

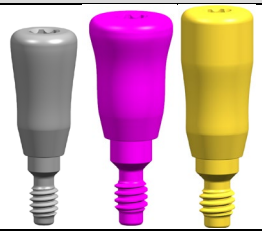
Characteristic	Subject Device	Predicate Device (Reference Device #5)	Reference Device #6	
	Temporary Abutments Engaging and Non-Engaging Conical Connection	Temporary Abutment Nobel Biocare N1™ TCC	Temporary Snap Abutment (Engaging and Non-Engaging)	Comparison:
		K211109	K161435	
Manufacturer	Nobel Biocare	Nobel Biocare	Nobel Biocare	
Intended Use				
Pictorial Representation				n/a
Product Classification	Class II	Class II	Class II	Same as Predicate Device (Reference Device #5)
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same as Predicate Device (Reference Device #5)
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same as Predicate Device (Reference Device #5)
Product Code, primary	NHA	NHA	NHA	Same as Predicate Device (Reference Device #5)
Review Panel	Dental	Dental	Dental	Same as Predicate Device (Reference Device #5)
Intended Use	Intended to be connected to an endosseous dental implant to support the placement of a dental prosthesis	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.	Same intended use, differing only in the choice of words

Characteristic	Subject Device	Predicate Device (Reference Device #5)	Reference Device #6	
	Temporary Abutments Engaging and Non-Engaging Conical Connection	**Temporary Abutment Nobel Biocare N1™ TCC**	**Temporary Snap Abutment (Engaging and Non-Engaging)**	**Comparison:**
		K211109	**K161435**	
Indications for Use	Temporary Abutment Engaging and Non-Engaging Temporary Abutments Engaging CC are indicated for use with single unit screw-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days. Temporary Abutment Non-Engaging CC are indicated for use with multiple unit screw-retained temporary dental prosthesis placed on endosseous dental implant in the maxilla and mandible, for up to 180 days.	Are indicated for use with single unit screw-retained temporary dental prostheses placed on endosseous dental implants in the maxilla and mandible, for up to 180 days.	Temporary Abutment Non-Engaging is a premanufactured prosthetic component directly connected to the endosseous dental implant and is intended for use as an aid in prosthetic rehabilitation. Temporary Abutment Non-Engaging Titanium is indicated for screw-retained multiple temporary restorations, for implants with less than 40° overall divergences to allow path of insertion.	Same indications use, differing only in the choice of words
Clinical setting	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	The finalized abutment is used in a dental practice	Same as Predicate Device (Reference Device #5)
Primary User Population	Dental healthcare professionals	Dental healthcare professionals	Dental healthcare professionals	Same as Predicate Device (Reference Device #5)
Patient Population	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Same as Predicate Device (Reference Device #5)
Anatomical Site	Oral cavity	Oral cavity	Oral cavity	Same as Predicate Device (Reference Device #5)
Technological Characteristics				
Device Dimensions/ Design Specifications				
Minimum gingiva height:	1.5 mm	1.5 – 3 mm	1.5 mm 3.0 mm	Same as Predicate Device (Reference Device #5)
Diameter:	NP Ø 4.1mm RP Ø 4.3mm / Ø 4.8 WP Ø 4.8mm	3.4 mm 3.7 mm	NP Ø 4.0mm RP Ø 4.5mm WP Ø 6.0mm	In range of Predicate Device (Reference Device #5) and Reference Device #6
Screw Channel	straight	straight	straight	Same as Predicate Device (Reference Device #5)
Abutment Shape	Standardized	Standardized	Standardized	Same as Predicate Device (Reference Device #5)
Platform compatibility	Narrow Platform (NP)	Narrow Platform (NP)	Narrow Platform (NP)	Same as Predicate Device (Reference Device #5)

Characteristic	Subject Device	Predicate Device (Reference Device #5)	Reference Device #6	
	Temporary Abutments Engaging and Non-Engaging Conical Connection	**Temporary Abutment Nobel Biocare N1™ TCC**	**Temporary Snap Abutment (Engaging and Non-Engaging)**	**Comparison:**
		K211109	**K161435**	
	Regular Platform (RP)	Regular Platform (RP)	Regular Platform (RP)	Same as Predicate Device (Reference Device #5)
	Wide Platform (WP)	N/A	Wide Platform (WP)	Same as Predicate Device (Reference Device #6)
Connection interface	Conical Connection	Nobel Biocare Tri-oval Conical Connection	Hexagonal Snap into Conical Connection	Similar as Reference Device #6. The connection interface has the same function as the connection of Predicate Device (Reference Device #5)
Attachment method to implant	Screw retained	Screw retained	Screw retained	Same as Predicate Device (Reference Device #5)
Restoration type	single-unit (engaging) multi-unit (non-engaging)	single-unit (non-engaging)	single-unit (engaging) multi-unit (non-engaging)	Same as Reference Device #6
Design features	Temporary Abutment fixed onto an implant with a clinical screw Single and Multi-unit	Temporary Abutment fixed onto an implant with a clinical screw Single-unit	Temporary Abutment fixed onto an implant with a clinical screw Single and Multi-unit	Same as Reference Device #6
Principle of operation/ Mechanism of action	Mechanical screw connection	Mechanical screw connection	Mechanical screw connection	Same as Predicate Device (Reference Device #5)
Maximum abutment angulation	0°	0°	0°	Same as Predicate Device (Reference Device #5)
Material Temporary Abutment	Titanium aluminum vanadium alloy	Titanium aluminum vanadium alloy	Titanium aluminum vanadium alloy	Same as Predicate Device (Reference Device #5)
	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Same as Predicate Device (Reference Device #5)
Surface treatment	Anodized	Anodized	Anodized (top part)	Same as Predicate Device (Reference Device #5)
Biocompatibility	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-1	Same as Predicate Device (Reference Device #5)
Tissue contact	Permanent contact with bone and soft tissue	Permanent contact with bone and soft tissue	Permanent contact with bone and soft tissue	Same as Predicate Device (Reference Device #5)
Shelf life	5 years	5 years	N/A – Delivered non-sterile	Same as Predicate Device (Reference Device #5)

Characteristic	Subject Device	Predicate Device (Reference Device #5)	Reference Device #6	
	Temporary Abutments Engaging and Non-Engaging Conical Connection	**Temporary Abutment Nobel Biocare N1™ TCC**	**Temporary Snap Abutment (Engaging and Non-Engaging)**	**Comparison:**
		K211109	**K161435**	
Sterility	Provided Sterile – Gamma Radiation SAL 10^{-6}	Provided Sterile – Gamma Radiation SAL 10^{-6}	Provided non-sterile – terminally sterilized via autoclave prior to implantation	Same as Predicate Device (Reference Device #5)
Single Use or Reusable	Single use	Single use	Single use	Same as Predicate Device (Reference Device #5)
MRI compatibility	MR Conditional	MR Conditional	MR Conditional	Same as Predicate Device (Reference Device #5)
	(cleared in K212125)	(cleared in K212125)	(cleared in K212125)	Same as Predicate Device (Reference Device #5)
Packaging				
Packaging	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Same as Predicate Device (Reference Device #5)
Co-Packing	co-packed with screw	co-packed with screw	co-packed with screw	Same as Predicate Device (Reference Device #5)

Table 5: Healing Abutment Predicate and Reference Device Summary

Characteristic	Subject Device	Predicate Device (Reference Device #7)	
	Healing Abutment Conical Connection	**Healing Abutment Conical Connection**	**Comparison:**
		K102436, K133731	
Manufacturer	Nobel Biocare	Nobel Biocare	
Intended Use			
Pictorial Representation			n/a
Product Classification	Class II	Class II	Same as Predicate Device (Reference Device #7)
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	Same as Predicate Device (Reference Device #7)
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same as Predicate Device (Reference Device #7)
Product Code, primary	NHA	NHA	Same as Predicate Device (Reference Device #7)
Review Panel	Dental	Dental	Same as Predicate Device (Reference Device #7)
Intended Use	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Healing Abutment and Healing Cap is intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.	Dental implant abutments are intended to be used in the upper or lower jaw and used for supporting tooth replacements to restore chewing function. Healing Abutment and Healing Cap is intended to be used as a temporary component to an endosseous implant to allow healing of the soft tissue.	Same as Predicate Device (Reference Device #7)
Indications for Use	The Healing Abutments and Healing Caps are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for one single tooth to full arch denture procedures.	The Healing Abutments and Healing Caps are premanufactured prosthetic components to be directly connected to the endosseous dental implants or abutments and are indicated as temporary components for one single tooth to full arch denture procedures.	Same as Predicate Device (Reference Device #7)
Clinical setting	The healing abutment is used in a dental practice	The healing abutment is used in a dental practice	Same as Predicate Device (Reference Device #7)
Primary User Population	Dental healthcare professionals	Dental healthcare professionals	Same as Predicate Device (Reference Device #7)

Characteristic	Subject Device	Predicate Device (Reference Device #7)	
	Healing Abutment Conical Connection	**Healing Abutment Conical Connection**	**Comparison:**
		K102436, K133731	
Patient Population	Patients Subject to dental implant treatment	Patients Subject to dental implant treatment	Same as Predicate Device (Reference Device #7)
Anatomical Site	Oral cavity	Oral cavity	Same as Predicate Device (Reference Device #7)
Technological Characteristics			
Device Dimensions/ Design Specifications			
Minimum gingiva height	3.0 mm, 5.0 mm	3.0 mm, 5.0 mm	Same as Predicate Device (Reference Device #7)
Diameter	3.3. – 6.4 mm	3.2 – 6.5 mm	In range of Predicate and Reference Device #7
Minimum post height:	No post	No post	Same as Predicate Device (Reference Device #7)
Screw Channel	straight	straight	Same as Predicate Device (Reference Device #7)
Abutment Shape	Standardized	Standardized	Same as Predicate Device (Reference Device #7)
Platform compatibility	3.0	3.0	Same as Predicate Device (Reference Device #7)
	Narrow Platform (NP)	Narrow Platform (NP)	Same as Predicate Device (Reference Device #7)
	Regular Platform (RP)	Regular Platform (RP)	Same as Predicate Device (Reference Device #7)
	Wide Platform (WP)	Wide Platform (WP)	Same as Predicate Device (Reference Device #7)
Connection interface	Conical Connection	Conical Connection	Same as Predicate Device (Reference Device #7)
Attachment method to implant	Healing Abutment (integrated screw) attaches to the implant Screw retained	Healing Abutment (integrated screw) attaches to the implant Screw retained	Same as Predicate Device (Reference Device #7)
Principle of operation/ Mechanism of action	Mechanical screw connection	Mechanical screw connection	Same as Predicate Device (Reference Device #7)
Interface	Unigrip	Unigrip	Same as Predicate Device (Reference Device #7)
Maximum abutment angulation	0° (straight)	0° (straight)	Same as Predicate Device (Reference Device #7)

Characteristic	Subject Device	Predicate Device (Reference Device #7)	
	Healing Abutment Conical Connection	**Healing Abutment Conical Connection**	**Comparison:**
		K102436, K133731	
Thread design	One-piece healing abutment • 3.0 M1.4x0.3-6h • NP NB – M1.6x0.35 • RP M2x0.4-6g • WP M2x0.4-6g	One-piece healing abutment • 3.0 M1.4x0.3-6h • NP NB – M1.6x0.35 • RP M2x0.4-6g • WP M2x0.4-6g	Same as Predicate Device (Reference Device #7)
Material	Titanium aluminum vanadium alloy	Titanium aluminum vanadium alloy	Same as Predicate Device (Reference Device #7)
	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Ti6Al4V ELI (ISO 5832-3, ASTM F136) MTA005	Same as Predicate Device (Reference Device #7)
Surface treatment	Anodized	Anodized	Same as Predicate Device (Reference Device #7)
Biocompatibility	biocompatible according to ISO 10993-1	biocompatible according to ISO 10993-1	Same as Predicate Device (Reference Device #7)
Tissue contact	Temporary during the healing time of the soft tissue	Temporary during the healing time of the soft tissue	Same as Predicate Device (Reference Device #7)
Shelf life	5 years	5 years	Same as Predicate Device (Reference Device #7)
Sterility	Provided sterile – Gamma Radiation SAL 10^{-6}	Provided sterile – Gamma Radiation SAL 10^{-6}	Same as Predicate Device (Reference Device #7)
Single Use or Reusable	Single use	Single use	Same as Predicate Device (Reference Device #7)
Packaging			
Packaging	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Thermoformed polyethylene terephthalate glycol (PETG) blister tray with medical paper lid forming a sterile barrier.	Same as Predicate Device (Reference Device #7)

<u>The similarities between the Subject Device line Temporary Abutment Engaging, Non-Engaging, Healing Abutments Conical Connection and the Predicate (Reference Devices # 5, 6 and 7) Device are as follows:</u>

- The Intended Use statement and Indications for Use statement are the same, differing only in the choice of words
- Principle of operations, design features and workflow, attachment methods, device material, compatible devices are the same or similar for the Subject Devices and the Predicate Devices. Furthermore, all the Subject and Predicate Devices are sterile, single-use devices.
- Subject Device Lines and the Primary Predicate Devices are labelled MR Conditional

Details of the Differences Between the Subject and Predicate Device:

There are no significant differences between the Subject and Predicate devices but there are minor differences as follows:

- The Subject Device can be used for a temporary multi-unit restoration, is anodized and the dimensions are different in the Subject and Predicate Device but remain in the range of the Predicate Device and Reference Device.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the device line Temporary Abutments is deemed to be substantially equivalent to the Primary Predicate. The new device does not introduce a fundamentally new scientific technology and the non-clinical tests demonstrate that the device is substantially equivalent.

1.13.3 Omnigrip Clinical Screw Titanium

Table 6: Omnigrip Clinical Screw Titanium and Predicate Device Summary

Characteristic	Subject Device	Predicate Device (Reference Device #8)	Reference Device #9	Comparison:
	Omnigrip Clinical Screw Titanium	**Omnigrip Clinical Screw Titanium**	**Clinical Screw Multi-unit Abut Nobel Biocare N1 TCC**	
510k		**K233208**	**K211109**	
Manufacturer	Nobel Biocare	Nobel Biocare	Nobel Biocare	
Pictorial Representation				n/a
Product Classification	Class II	Class II	Class II	Same as Predicate Device (Reference Device #8)
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same as Predicate Device (Reference Device #8)
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same as Predicate Device (Reference Device #8)
Product Code, primary	NHA	NHA	NHA	Same as Predicate Device (Reference Device #8)
Review Panel	Dental	Dental	Dental	Same as Predicate Device (Reference Device #8)
Intended Use	Intended for use to fasten dental implant system components to a dental implant or to another component.	The Clinical Screw, Abutment Screw and Prosthetic Screw are intended to secure a dental abutment or framework to a dental implant or abutment in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.	The Clinical Screw, Abutment Screw and Prosthetic Screw are intended to secure a dental abutment or framework to a dental implant or abutment in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.	Same intended use, differing only in the choice of words

Characteristic	Subject Device	Predicate Device (Reference Device #8)	Reference Device #9	Comparison:
	Omnigrip Clinical Screw Titanium	**Omnigrip Clinical Screw Titanium**	**Clinical Screw Multi-unit Abut Nobel Biocare N1 TCC**	
Indications for Use	Clinical/Prosthetic screws are indicated for use to secure a dental abutment or framework to a dental implant, abutment or base in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	The Clinical Screw, Abutment Screw and Prosthetic Screw are to be directly connected to the dental abutment or framework, intended for use as an aid in prosthetic rehabilitation.	The Clinical Screw, Abutment Screw and Prosthetic Screw are to be directly connected to the dental abutment or framework, intended for use as an aid in prosthetic rehabilitation.	Same indications use, differing only in the choice of words
Design Feature				
Screw body dimensions	Largest nominal diameter: NP: 2.3 RP/WP: 2.525 Nominal total length: NP: 9.475 RP/WP: 9.45	Largest nominal diameter: 2.375 – 2.525 Nominal total length: 8.905 – 8.705	Largest nominal diameter: 2.25 Nominal total length: 9.702 – 12.772	In range of Predicate Device (Reference Device #8) and Reference Device # 9
Thread design	CC NP: M1.6 x 0.35 CC RP / WP: M2 x 0.4	CC NP: M1.6 x 0.35 CC RP / WP: M2 x 0.4	NP: M1.4 x 0.2 RP: M1.6x0.2	Same as Predicate Device (Reference Device #8)
Anatomical Site	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Narrow Platform (NP) Regular Platform (RP) Wide Platform (WP)	Narrow Platform (NP) Regular Platform (RP)	Same as Predicate Device (Reference Device #8)
Screw Interface	Omnigrip	Omnigrip	Multi-unit	Same as Predicate Device (Reference Device #8)
Principle of operation (Attachment method)	The Omnigrip clinical screws are used for securing the abutment to the endosseous implant.	The Omnigrip clinical screws are used for securing the abutment to the endosseous implant.	The Omnigrip clinical screws are used for securing the abutment to the endosseous implant.	Same as Predicate Device (Reference Device #8)
Device material	Titanium vanadium alloy (Ti6Al4V ELI, ASTM F136-13 / ISO 5832)	Titanium vanadium alloy (Ti6Al4V ELI, ASTM F136-13 / ISO 5832)	Titanium vanadium alloy (Ti6Al4V ELI, ASTM F136-13 / ISO 5832)	Same as Predicate Device (Reference Device #8)

Characteristic	Subject Device	Predicate Device (Reference Device #8)	Reference Device #9	Comparison:
	Omnigrip Clinical Screw Titanium	**Omnigrip Clinical Screw Titanium**	**Clinical Screw Multi-unit Abut Nobel Biocare N1 TCC**	
Surface material	NP: N/A (machined surface, no PVD (DLC) coating) RP/WP: PVD (DLC) surface treatment	NP: N/A (machined surface, no PVD (DLC) coating) RP/WP: PVD (DLC) surface treatment	NP/RP: PVD (DLC) surface treatment	Same as Predicate Device (Reference Device #8)
Sterilization at supply (Standalone Device)	Provided non sterile	Provided non sterile	Provided sterile	Same as Predicate Device (Reference Device #8)
Initial processing	The Device should be cleaned and sterilized according to Instruction for use (IFU) guidelines	The Device should be cleaned and sterilized according to Instruction for use (IFU) guidelines	N/A	Same as Predicate Device (Reference Device #8)
Reusability	The product is for single use	The product is for single use	The product is for single use	Same as Predicate Device (Reference Device #8)
Packaging	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid.	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid.	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid.	Same as Predicate Device (Reference Device #8)
Duration of use	Permanent Use	Permanent Use	Permanent Use	Same as Predicate Device (Reference Device #8)
Shelf Life	N/A (non-sterile and non-organic, non-degradable component)	N/A (non-sterile and non-organic, non-degradable component)	5 years	Same as Predicate Device (Reference Device #8)
User	The Devices are to be used by dental health care professionals.	The Devices are to be used by dental health care professionals.	The Devices are to be used by dental health care professionals.	Same as Predicate Device (Reference Device #8)

Table 7: MUA Prosthetic Screw and Predicate Device Summary

Characteristic	Subject Device	Predicate Device (Reference Device #10)	Predicate Device (Reference Device #11)	Comparison
	Omnigrip Prosthetic Screw	**Prosthetic Screw NobelProcera Zr Nobel Biocare N1 Base**	**Prosthetic Screw MUA Omnigrip Mini**	
		K220048	**K202452**	
Manufacturer	Nobel Biocare	Nobel Biocare	Nobel Biocare	
Intended Use				
Pictorial Representation				n/a
Product Classification	Class II	Class II	Class II	Same as Predicate Device (Reference Device #10)
Regulation Number / Name	21 CFR 872.3630	21 CFR 872.3630	21 CFR 872.3630	Same as Predicate Device (Reference Device #10)
	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Endosseous Dental Implant Abutment	Same as Predicate Device (Reference Device #10)
Product Code, primary	NHA	NHA	NHA	Same as Predicate Device (Reference Device #10)
Review Panel	Dental	Dental	Dental	Same as Predicate Device (Reference Device #10)
Intended Use	Intended for use to fasten dental implant system components to a dental implant or to another component.	The Prosthetic Screw is intended to secure a dental abutment or framework to a dental implant or abutment in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.	The Prosthetic Screw is intended to secure a dental abutment or framework to a dental implant or abutment in the upper or lower jaw and used for supporting tooth replacements to restore chewing function.	Same intended use, differing only in the choice of words
Indications for Use	Clinical/Prosthetic screws are indicated for use to secure a dental abutment or framework to a dental implant, abutment or base in the maxilla or mandible for supporting tooth replacements and are indicated as an aid in prosthetic rehabilitation.	The Prosthetic Screw is to be directly connected to the dental abutment or crown, indicated for use as an aid in prosthetic rehabilitation	The Prosthetic Screw is to be directly connected to the dental abutment or crown, indicated for use as an aid in prosthetic rehabilitation	Same indications use, differing only in the choice of words

Characteristic	Subject Device	Predicate Device (Reference Device #10)	Predicate Device (Reference Device #11)	Comparison
	Omnigrip Prosthetic Screw	**Prosthetic Screw NobelProcera Zr Nobel Biocare N1 Base**	**Prosthetic Screw MUA Omnigrip Mini**	
Design Feature				
Screw body dimensions	Largest nominal diameter: 2.3 Nominal total length: 4.125	Largest nominal diameter: 2.68 – 2.88 Nominal total length: 4.54	Largest nominal diameter: 2.03 – 2.475 Nominal total length: 4.025 – 4.6	In range of Predicate Device (Reference Device #10) and Reference Device #11
Thread design	MUA NP/RP/WP: M1.4 x 0.3	NP: M2x0.2 mm RP: M2.2x0.2 mm	NP/RP: M1.4x0.3 mm WP: M1.8x0.35 mm	In range of Predicate Device (Reference Device #10) and Reference Device #11
Anatomical Site	MUA on NP/RP/WP	NP, RP	NP/RP, WP	Similar as Predicate Device (Reference Device #10)
Screw Interface	Omnigrip	Omnigrip Mini	Omnigrip Mini	Similar as Predicate Device (Reference Device #10)
Principle of operation (Attachment method)	The Omnigrip prosthetic screws are used for securing the Universal Base MUA to the Multi-unit Abutments.	The Prosthetic Screws NobelProcera® Zr NB N1™ Base are used to fix the NobelProcera® Zirconia N1™ Base Abutment / Implant Crown to the N1 Base abutment.	The Prosthetic Screws MUA Omnigrip Mini are used to fix the NobelProcera Zirconia Implant Bridge to a Multi-Unit Abutment	Similar as Predicate Device (Reference Device #10)
Device material	Titanium vanadium alloy (Ti6Al4V ELI, ASTM F136-13 / ISO 5832)	Titanium vanadium alloy (Ti6Al4V ELI, ASTM F136-13 / ISO 5832)	Titanium vanadium alloy (Ti6Al4V ELI, ASTM F136-13 / ISO 5832)	Same as Predicate Device (Reference Device #10)
Surface material	PVD (DLC) surface treatment	PVD (DLC) surface treatment	PVD (DLC) surface treatment	Same as Predicate Device (Reference Device #10)
Sterilization at supply (Standalone Device)	Provided non sterile	Provided non sterile	Provided non sterile	Same as Predicate Device (Reference Device #10)
Initial processing	The Device should be cleaned and sterilized according to Instruction for use (IFU) guidelines	The Device should be cleaned and sterilized according to Instruction for use (IFU) guidelines	The Device should be cleaned and sterilized according to Instruction for use (IFU) guidelines	Same as Predicate Device (Reference Device #10)
Reusability	The product is for single use	The product is for single use	The product is for single use	Same as Predicate Device (Reference Device #10)
Packaging	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid.	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid	Polyethylene terephthalate glycol (PETG) blister sealed with a medical Tyvek lid	Same as Predicate Device (Reference Device #10)
Duration of use	Permanent Use	Permanent Use	Permanent Use	Same as Predicate Device (Reference Device #10)

Characteristic	Subject Device	Predicate Device (Reference Device #10)	Predicate Device (Reference Device #11)	Comparison
	Omnigrip Prosthetic Screw	**Prosthetic Screw NobelProcera Zr Nobel Biocare N1 Base**	**Prosthetic Screw MUA Omnigrip Mini**	
Shelf Life	N/A (non-sterile and non-organic, non-degradable component)	N/A (non-sterile and non-organic, non-degradable component)	N/A (non-sterile and non-organic, non-degradable component)	Same as Predicate Device (Reference Device #10)
User	The Devices are to be used by dental health care professionals.	The Devices are to be used by dental health care professionals.	The Devices are to be used by dental health care professionals.	Same as Predicate Device (Reference Device #10)

The similarities between the Omnigrip Clinical Screw Titanium, Omnigrip Prosthetic Screw and the Predicate (Reference Devices # 9, 10 and 11) Devices are as follows:

- The Intended Use statement and Indications for Use statement are the same, differing only in the choice of words
- Principle of operations, design features and workflow, attachment methods, device material, compatible devices are the same or similar for the Subject Devices and the Predicate Devices. Furthermore, all the Subject and Predicate Devices are non-sterile, single-use devices.
- Subject Device Lines and the Primary Predicate Devices are labelled MR Conditional

Details of the Differences Between the Subject and Predicate device:

There are no significant differences between the Subject and predicate devices but there are minor differences as follows:

- The Subject Device and Predicate Device have different screw body dimensions.
- The Subject Device (Omnigrip Prosthetic Screw) is used to screwing the Universal Base MUA onto a Multi-unit Abutment while the Predicate Device is used to screw a NobelProcera Abutment onto an N1 Base Abutment, both devices are designed to secure components within a dental implant system.

Conclusion:

Based on a comparison of intended use, indications for use, technological characteristics, principle of operation, features, and performance data, the device line Screws is deemed to be substantially equivalent to the Primary Predicate. The new device does not introduce a fundamentally new scientific technology and the non-clinical tests demonstrate that the device is substantial equivalent.

1.14 Non-Clinical and/or Clinical Tests Summary & Conclusions:

Non-clinical testing was performed on the Subject device lines Universal Base ASC, Temporary Abutments and Screws:

- Packaging system performance validation according to ISO 11607-1, ISO 11607-2, ASTM D4169, ASTM D4332, ASTM F1886 and ASTM F2096 and shelf-life validation per ASTM F1980.
- Sterilization validation according to ISO 11137-1, ISO 11137-2, ISO 11137-3, AAMI TIR29 and AAMIT TIR 35.
- End user cleaning and sterilization validation in in accordance with ISO 17665-1
- Dynamic loading testing performed according to ISO 14801 and the FDA Guidance Document entitled, “Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments” (May 12, 2004)
- Magnetic Resonance compatibility testing according to ASTM F2052, ASTM F2213, ASTM F2119 and ASTM F2182
- Verification of biocompatibility of the final device in accordance with ISO 10993-1
- Software Verification and End-to-End Validation

Clinical performance data is not required to establish substantial equivalence of the Subject Devices.

Based on a comparison of intended use, indications, material composition, technological characteristics, principle of operation, features and performance data, the device lines Universal Base ASC, Temporary Abutments and Screws are deemed to be substantially equivalent to the Predicate Devices. The technological differences do not raise new questions of safety and effectiveness.