B.T.I. Biotechnology Institute, S.L.
Jose Rivero
Technical Manager
Leonardo Da Vinci 14
Minano, Alava 01510
SPAIN

December 8, 2023

Re: K232750
Trade/Device Name: BTI Interna Prosthetic Components
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: September 8, 2023
Received: September 8, 2023

Dear Jose Rivero:

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

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

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

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

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

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K232750

Device Name
BTI Interna Prosthetic Components

Indications for Use *(Describe)*
The BTI Interna Prosthetic Components are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on the BTI Interna Dental Implant System.

All digitally designed zirconia component for use with Aesthetic post abutments are to be sent to a BTI validated milling center for manufacture.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY – K232750

1. SUBMITTER INFORMATION

Name and address:	B.T.I. Biotechnology Institute, SL. Parque Tecnológico de Álava C/Leonardo Da Vinci 14 01510 Miñano (Álava), Spain
Phone:	(+34) 945 297 030
Fax:	(+34) 945 297 031
Contact person:	Mr. José Ramón Rivero, Technical Manager

Date prepared:	December 8, 2023

2. DEVICE NAME AND CLASSIFICATION

Name of device:	BTI Interna Prosthetic Components
Regulation Number:	21 CFR 872.3630
Regulation Name:	Endosseous dental implant abutment
Regulatory Class:	Class II
Product Code:	NHA
Classification Panel:	Dental

3. PREDICATE DEVICES

Primary predicate device:

- K213106 BTI Interna Dental Implant System UnicCa - Prosthetic Components, B.T.I. Biotechnology Institute, SL.

Reference devices:

- K231827 BTI Dental Implant System UnicCa® – Aesthetic Post Abutments
- K211952 BTI Interna Narrow/Plus Dental Implant System UnicCa, B.T.I. Biotechnology Institute, SL.
- K203240 AccelX Abutments, Integrated Dental Systems LLC
- K191123 Multi-unit Abutments, Medentika GmbH
- K053355 BTI Interna Dental Implant System, B.T.I. Biotechnology Institute, SL.
- K171142 Healing Cap Multi-Unit Titanium, Nobel Biocare AB
- K212108 Dynamic TiBase, Talladium España, SL
- K202825 BTI Extra-Short Dental Implant System UnicCa, B.T.I. Biotechnology Institute, SL.
- K173257 BTI Dental Implant System UnicCa, B.T.I. Biotechnology Institute, SL.
- K151391 BTI Dental Implant System UnicCa, B.T.I. Biotechnology Institute, SL.

4. INDICATIONS FOR USE

The BTI Interna Prosthetic Components are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on the BTI Interna® Dental Implant System.

All digitally designed zirconia components for use with Aesthetic post abutments are to be sent to a BTI validated milling center for manufacture.

5. DEVICE DESCRIPTION

The purpose of this 510(k) is to expand the BTI product offering and include a variety of abutments compatible with the already cleared BTI Dental Implant System implants. Subject device abutments include 15º Angled abutments, Transepithelial abutments, Temporary titanium abutments, Healing caps, Aesthetic post abutments and Screws. Aesthetic post abutments include Square abutments and Aesthetic interfaces for Transepithelials, as the bottom part of a two-piece abutment. A zirconia superstructure fabricated through CAD-CAM technology is the upper part of the two-piece abutment.

The subject 15º Angled Titanium abutments are designed to be connected to a BTI Interna Narrow implant, to hold single and multiple cement-retained restorations. The compatible BTI implants have been previously cleared in K211952. The abutments are offered with a 15º angulation and gingival heights of 3.0, 4.0, and 5.0 mm. They are manufactured in commercially pure titanium, with a TiN coating to enhance abutment aesthetic appearance.

The subject Temporary abutments are designed for single-unit and multi-unit screw-retained restorations on Transepithelial abutments. The abutments are offered in prosthetic diameters of 3.5, 5.0 and 5.5 mm, with no angulation. They are manufactured from commercially pure titanium.

The subject Transepithelial abutments are designed for single-unit and multi-unit screw-retained restorations on previously cleared BTI implants. The compatible BTI implants have been previously cleared in K211952, K202825, K173257, and K151391. They are available in an engaging and a non-engaging connection. They are offered in a prosthetic platform diameter of 3.5, 5.0 and 5.5 mm, and gingival heights ranging from 0.5 to 5.0 mm, with 0º, 17º and 30º angulation. They are manufactured from commercially pure titanium, with a TiN coating on abutment surface. The retention screw is provided with the abutment and is manufactured from titanium alloy with a DLC coating.

The subject Healing caps are designed to be connected to a Transepithelial abutment implant during the healing period, between Transepithelial placement and final dental restoration placement. These abutments are provided in prosthetic diameters of 3.5 and 5.0 mm. They are manufactured from commercially pure titanium and anodized.

The subject Aesthetic interfaces are two-piece abutments composed of a bottom half titanium component, and a patient-specific designed CAD-CAM zirconia superstructure as a top half component. The Aesthetic interfaces are to be attached to a Transepithelial abutment to hold single or multi-unit restorations. They are fabricated from commercially pure titanium, with a TiN coating to enhance abutment aesthetic appearance.

The design parameters for this top-half abutment fabrication are as follows:

- Minimum wall thickness: 0.4 mm
- Minimum post height for single-unit restorations: 4.0 mm
- Minimum gingival height: 0 mm in the zirconia superstructure
- Maximum gingival height: 6.0 mm
- Maximum angulation: 0º

The subject Square abutments are two-piece abutments, composed of a bottom half titanium component, and a patient-specific designed CAD-CAM zirconia superstructure as a top half component. The Square abutments are to be attached to a BTI implant to hold single or multi-unit restorations. The compatible BTI implants have been previously cleared in K211952, K202825, K173257, and K151391. They are fabricated from commercially pure titanium, with a TiN coating to enhance abutment aesthetic appearance. The subject Square abutments are straight abutments (0º), and are provided in a variety of gingival heights ranging from 0.5 mm to 3.0 mm.

The design parameters for this top-half abutment fabrication are as follows:

- Minimum wall thickness: 0.4 mm
- Minimum post height for single-unit restorations: 4.0 mm
- Minimum gingival height: 0 mm in the zirconia superstructure
- Maximum gingival height: 6.0 mm

- Maximum angulation: 0º

The zirconia superstructures for use with the subject Square abutments and Aesthetic Interfaces will be made at a BTI validated milling center and the material will conform to ISO 13356. The bonding cement recommended for the zirconia superstructure is Multilink Hybrid Abutment Cement (Ivoclar Vivadent AG), cleared in K130436.

The subject Screws are designed to attach Square abutments and Aesthetic Interfaces to the compatible BTI dental implant or Transepithelial abutment, respectively. The Screws are manufactured from titanium alloy, with a DLC coating on screw thread. One subject Screw is also anodized for ease identification.

6. PERFORMANCE DATA

Non-clinical testing information submitted or referenced in order to demonstrate substantial equivalence of the proposed device include:

- Moist heat sterilization validation for the subject device components provided non-sterile to the end user, to a sterility assurance level of 10^{-6} by the overkill method, according to ANSI/AAMI/ISO 17665-1, ANSI/AAMI/ISO TIR 17665-2, and ANSI/AAMI/ISO 14937.
- Sterilization Validation for subject device components provided sterile, to a sterility assurance level (SAL) of 10-6, according to ISO 11137-1, ISO 11137-2 and ISO 17665-1.
- Biocompatibility testing according to ISO 10993-5 and ISO 10993-12 for the final Aesthetic post abutment (unalloyed titanium base and bonded zirconia superstructure).
- Mechanical testing according to ISO 14801.
- Coating characterization according to the recommendations in FDA Guidance Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments, issued May 12, 2002.
- Non-clinical worst-case MRI analysis to evaluate the subject device components in the MR environment using scientific rationale and published literature (T.O. Woods, J.G. Delfino, and S. Rajan, “Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices,” Journal of Testing and Evaluation Volume 49, No. 2 (March/April 2021): 783–795), based on the entire system including all variations (all compatible implant bodies, abutments, and fixation screws) and material composition. Rationale addressed parameters per the FDA guidance Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment, including magnetically induced displacement force and torque.

No clinical data were included in this submission.

7. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE DISCUSSION

The proposed device is substantially equivalent in Indications for Use, operating principle and design to the primary predicate and reference devices identified above. Table 5-1 and Table 5-2 below compare the subject device to selected predicate and reference devices indications for use and technological characteristics.

The subject 15º Angled abutments are substantially equivalent to those cleared in K213106 in Indications for use, material, surface coating and angulation. The BTI Interna Narrow/Plus Dental Implant System UnicCa® is identified for compatibility with the BTI Interna Narrow implant platform, and the AccelX Abutments are identified for support of substantial equivalence for gingival height of 5.0 mm.

The subject Transepithelial abutments are substantially equivalent to those cleared in K211952. Additional Transepithelial abutments cleared under K213106 are identified for support of compatibility with the prosthesis Ø5.5 mm. Additionally, the Medentika Multi-Unit abutments, cleared in K191123, are identified for support of gingival height of 0.5 and 5.0 mm in subject device.

The subject Temporary titanium abutments are equivalent to those previously cleared in K211952. The BTI Interna Dental Implant System, cleared in K053355, is identified as it includes temporary abutments with similar prosthetic diameter as subject device.

The subject Healing caps are substantially equivalent to those designs cleared in K211952. The Nobel Healing Cap Multi-Unit Titanium, cleared in K171142 is identified for support of abutment height of 5.0 in subject device.

The subject Square abutments and Interfaces (jointly designated as Aesthetic post abutments) are substantially equivalent to those previously cleared in K231827 in Indications for use, materials of manufacture, surface treatment applied, implant/abutment compatibility and prosthetic diameters. The Dynamic Ti Base, cleared in K212108 is identified for support of specific abutment design features.

The subject Screws are substantially equivalent to the screws previously cleared in K213106 and K211952 in Indications for use, materials, abutment coating applied and key dimensions.

8. CONCLUSIONS

The subject device components have similar Indications for use and technological characteristics of primary predicate device and reference devices identified above. The subject device components encompass a similar range of dimensions, designs, include identical materials, and are sterilized using similar methods.

The information included in this submission demonstrate that the subject BTI Interna Prosthetic components are substantially equivalent to the identified predicate devices.

Table 5-1. Substantial Equivalence – Indications for use comparison

<table>
<tr><th>Device</th><th>Indications for Use Statement</th></tr>
<tr><td>Subject device</td><td>The BTI Interna Prosthetic Components are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on the BTI Interna® Dental Implant System.
All digitally designed zirconia components for use with Aesthetic post abutments are to be sent to a BTI validated milling center for manufacture.</td></tr>
<tr><td>Primary predicate device
BTI Interna Dental Implant System UnicCa - Prosthetic Components
K213106</td><td>The BTI Intema Dental Implant System UnicCa® - Prosthetic Components are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on the BTI Intema® Dental Implant System.</td></tr>
<tr><td>Reference device
BTI Dental Implant System UnicCa® – Aesthetic Post Abutments
K231827</td><td>The BTI Interna Dental Implant System UnicCa® - Prosthetic Components are intended to function in the mandible or maxilla to support single and multiple-unit temporary or definitive restorations on the BTI Interna® Dental Implant System implants.
All digitally designed zirconia components for use with Square Aesthetic Abutments and Aesthetic Interfaces for Transepithelials are to be sent to a BTI validated milling center for manufacture.</td></tr>
<tr><td>Reference device
BTI Interna Narrow/Plus Dental Implant System UnicCa
K211952</td><td>The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient’s mastication function.
In the case of 5.5 – 6.5mm long UnicCa® implants: These implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations.
In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.</td></tr>
<tr><td>Reference device
BTI Interna Dental Implant System
K053355</td><td>Dental implant system comprising endosseous titanium implants and prosthetic elements to be attached to the implants, as well as auxiliary elements for surgical and prosthetic procedures.
The intended use of the system is the restoration of missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.</td></tr>
<tr><td>Reference device
AccelX Abutments
K203240</td><td>AccelX™ Abutments are intended to be used in conjunction with endosseous dental implants in the maxillary or mandibular arch to provide support for single-unit or multi-unit prosthetic restorations.
All digitally designed abutments for use with AccelX™ CAD-CAM Abutments are intended to be sent to an Integrated Dental Systems validated milling center for manufacture.
AccelX™ Abutments are compatible with MegaGen AnyRidge Internal Implant System components as listed below.
<table>
<tr><th>Implant System Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr>
<tr><td rowspan="10">MegaGen AnyRidge Internal Implant System</td><td>4.0</td><td>3.5</td></tr>
<tr><td>4.4</td><td>3.5</td></tr>
<tr><td>4.9</td><td>3.5</td></tr>
<tr><td>5.4</td><td>3.5</td></tr>
<tr><td>5.9</td><td>3.5</td></tr>
<tr><td>6.4</td><td>5.0</td></tr>
<tr><td>6.9</td><td>5.0</td></tr>
<tr><td>7.4</td><td>5.0</td></tr>
<tr><td>7.9</td><td>5.0</td></tr>
<tr><td>8.4</td><td>5.0</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td>Reference device
Healing Cap Multi-Unit Titanium
K171142</td><td>The Healing Cap Multi-unit Titanium is a premanufactured prosthetic component to be directly connected to the dental abutment during soft tissue healing to protect the internal connection of the abutments and prepare the soft tissue for the prosthetic procedure. Maximum intra-oral use is 180-days.</td></tr>
<tr><td>Reference device
Dynamic TiBase
K212108</td><td>Dynamic TiBase abutments are intended for use with dental implants as a support for single-unit or multi-unit prostheses in the maxillary or mandibular arch of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform, mm</th></tr>
<tr><td rowspan="4">SPI® CONTACT Dental Implant</td><td>2.7</td><td>3.5</td></tr>
<tr><td>3.5</td><td>4.0</td></tr>
<tr><td>3.5</td><td>4.5</td></tr>
<tr><td>4.2</td><td>5.0</td></tr>
</table>
All digitally designed custom abutments for use with Dynamic TiBase abutments are to be sent to a Thommen Medical validated milling center for manufacture.</td></tr>
<tr><td>Reference device
Multi-unit Abutments
K191123</td><td>Multi-unit abutments are indicated for use with dental implants as a support for multi-unit screw retained bridges and bars in the maxilla or mandible of a partially or fully edentulous patient.
Multi-unit Abutments are used for the restoration of the following dental implant systems:
<table>
<tr><th>Medentika series</th><th>Implant system</th><th>Implant diameter</th><th>Platform diameter</th></tr>
<tr><td>EV-Series</td><td>Dentsply® Implants - ASTRA TECH OsseoSpeed®</td><td>3.6, 4.2, 4.8</td><td>3.6, 4.2, 4.8</td></tr>
<tr><td>F-Series</td><td>Nobel Biocare NobelActive - NobelReplace Conical</td><td>3.5, 4.3, 5.0</td><td>NP 3.5, RP 4.3/5.0</td></tr>
<tr><td>H-Series</td><td>Biomet 3i - Certain</td><td>3.25, 4.0</td><td>3.4, 4.1</td></tr>
<tr><td>L-Series</td><td>Straumann - Bone Level</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>N-Series</td><td>Straumann - Soft Tissue Level</td><td>4.1, 4.8</td><td>4.8, 6.5</td></tr>
<tr><td>R-Series</td><td>Zimmer Dental Tapered Screw-vent</td><td>3.3, 3.7, 4.1, 4.7</td><td>3.5, 4.5</td></tr>
</table></td></tr>
</table>

Table 5-2. 15º Angled Biobutments. Substantial Equivalence – Technological characteristics comparison.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Name	**BTI Interna Prosthetic Components**	**BTI Interna Dental Implant System UnicCa®- Prosthetic components (K213106)**	**BTI Interna Narrow/Plus Dental Implant System UnicCa (K211952)**	**AccelX™ Abutments (K203240)**
Product Classification	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: DZE, NHA Regulation No.: 21 CFR 872.3640, 21 CFR 872.3630 Device Class II	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II
Material	Commercially pure titanium, Grade 4.	Commercially pure titanium, Grade 4.	Commercially pure titanium, Grade 4.	Ti-Al-4V alloy conforming to ASTM F136
Surface treatment / Andization	Titanium Nitride (TiN)	Titanium Nitride (TiN)	Titanium Nitride (TiN)	(Not known)
Restoration	Single and multiple	Single and multiple	Single and multiple	Single and multiple
Abutment fixation	Screw retained	Screw retained	Screw retained	Screw retained
Abutment / Implant Connection	Internal Engaging	Internal Engaging	Internal Engaging	Internal
Compatible Implant Platform	Interna®Narrow Ø=3.5mm	Interna®Wide Ø=5.5mm	Interna®Narrow Ø=3.5mm	MegaGen AnyRidge Internal Implant System (platform Ø=3.5, 5.0 mm)
Gingival height (mm)	3.0, 4.0, 5.0	2.0, 4.0	3.0, 4.0	2 - 5 (Angled abutments)
Abutment angulation	15º	15º	0°	15°, 25º (Angled abutments)
Prosthetic Ø (mm)	3.75 / 4.2	5.5	3.5, 4.2	4 – 7 (Angled abutments)
Supplied Sterile	No	Yes	No	No
Sterilization	To be sterilized by end user - steam sterilization	Gamma irradiation	To be sterilized by end user - steam sterilization	To be sterilized by end user - steam sterilization
Packaging	Thermosealed plastic bag	Thermoform tray with peel top lid (PETG + TYVEK)	Thermosealed plastic bag	(Not known)

Table 5-3. Temporary titanium abutments. Substantial Equivalence – Technological characteristics comparison.

FEATURE	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Name	**BTI Interna Prosthetic Components**	**BTI Interna Narrow/Plus Implant System (K211952)**	**BTI Interna Dental Implant System (K053355)**
Product Classification	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: DZE, NHA Regulation No.: 21 CFR 872.3640, 21 CFR 872.3630 Device Class II	Product Code: DZE - Implant, Endosseous, Root-Form Regulation No.: 21 CFR 872.3640 Device Class II
Material	Commercially pure titanium, Grade 4	Commercially pure titanium, Grade 4	Commercially pure titanium, Grade 4
Restoration	Single and Multiple	Single and Multiple	Single and Multiple
Abutment fixation	Screw retained	Screw retained	Screw retained
Length (mm)	12	12	Maximum length 14.3
Abutment angulation	0°	0°	0°
Prosthetic Ø (mm)	3.5, 5.0, 5.5	3.5, 4.1	5 - 6.3
Supplied Sterile	No	No	No
Sterilization	To be sterilized by the end user by moist heat	To be sterilized by the end user by moist heat	To be sterilized by the end user by moist heat
Packaging	Thermosealed plastic bag	Thermosealed plastic bag	Thermosealed plastic bag

Table 5-4. Healing caps. Substantial Equivalence – Technological characteristics comparison.

FEATURE	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Name	**BTI Interna Prosthetic Components**	**BTI Interna Narrow Implant System (K211952)**	**Healing Cap Multi-Unit Titanium (K171142) (Nobel)**
Product Classification	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: DZE, NHA Regulation No.: 21 CFR 872.3640, 21 CFR 872.3630 Device Class II	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II
Material	Commercially pure titanium, Grade 4.	Commercially pure titanium, Grade 4.	Titanium alloy Ti6Al4V ELI
Surface treatment / Anodization	Color anodization for Straight Mutli-Unit Non anodized for Angled Multi-unit	Color anodization for those caps used on top of selected Multi-unit (single-unit)	None (not specified in the 510(k) Summary)
Abutment fixation	Screw retained	Screw retained	Screw retained
Abutment Height (mm)	3.5, 5.0	3.0, 4.0	4.1 and 5.5 mm
Abutment Ø (mm)	3.5, 5	3.5, 4.1	5.0, 6.0, 6.9
Supplied Sterile	No	No	Yes
Sterilization	To be sterilized by the end user by moist heat	To be sterilized by the end user by moist heat	Gamma irradiation
Packaging	Thermosealed plastic bag	Thermosealed plastic bag	Thermoform tray with peel top lid

Table 5-5. Square abutments. Substantial Equivalence – Technological characteristics comparison.

FEATURE	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Name	**BTI Interna Prosthetic Components**	**BTI Dental Implant System UnicCa® – Aesthetic Post Abutments (K231827)**	**BTI Interna Narrow Implant System (K211952)**	**Dynamic Ti Base (K212108)**
Product Classification	Product Code: NHA Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: NHA Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: DZE, NHA Regulation No.: 21 CFR 872.3640, 21 CFR 872.3630 Device Class II	Product Code: NHA Regulation No.: 21 CFR 872.3630 Device Class II
Material	Commercially pure titanium, Grade 4 Zirconia, ISO 13356	Commercially pure titanium, Grade 4 Zirconia, ISO 13356	Commercially pure titanium, Grade 4	Titanium alloy (Ti-6Al-4V) Zirconia, ISO 13356
Surface treatment / Andization	Titanium Nitride (TiN)	Titanium Nitride (TiN)	Titanium Nitride (TiN)	Anodization
Restoration	Single and Multiple	Single and Multiple	Single and Multiple	Single and Multiple
Abutment fixation	Screw retained	Screw retained	Screw retained	Screw retained
Abutment / Implant Connection	Internal Engaging and Non Engaging	Internal Engaging and Non Engaging	Internal Engaging and Non Engaging	Internal Engaging and Non Engaging
Compatible Implant Platform	Interna®Narrow Ø=3.5mm Interna®Universal and Universal Plus Ø=4.1mm	Interna®Universal and Universal Plus Ø=4.1mm Interna®Wide Ø=5.5mm	Interna®Narrow Ø=3.5mm	(See Indications for Use above)
Height (prosthetic, mm)	6.5 (shortable up to 4 mm when used for single-unit restoration)	3.5	3.5	(maximum height) / (cutout height): 4.0 / 3.3 mm 9.0 / 3.5 mm (shortable up to 4 mm for single unit)
Gingival Height	0.5 - 3.0	0.5 - 3.5	0.5 - 3.5	0.7
Prosthetic Ø (mm)	3.76, 3.95, 4.42, 4.4, 4.8	4.8, 5.9	4 (also includes other titanium abutments of prosthetic diameter ranging from 3.5 to 4.2)	(prosthetic platform diameter): 4.1, 4.3, 4.75, 5.25

FEATURE	SUBJECT DEVICE	REFERENCE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Name	**BTI Interna Prosthetic Components**	**BTI Dental Implant System UnicCa® – Aesthetic Post Abutments (K231827)**	**BTI Interna Narrow Implant System (K211952)**	**Dynamic Ti Base (K212108)**
Abutment angulation	0º	0º	0º	0º
Supplied Sterile	No	No	No	No
Sterilization	To be sterilized by the end user by moist heat	To be sterilized by the end user by moist heat	To be sterilized by the end user by moist heat	To be sterilized by the end user by moist heat
Packaging	Thermoform tray with peel top lid (PETG + TYVEK)	Thermosealed bag	Thermosealed bag (for sterile components, a Thermoform tray with peel top lid (PETG + TYVEK) is used)	Unknown

Table 5-6. Transepithelial abutments. Substantial Equivalence – Technological characteristics comparison.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Name	**BTI Interna Prosthetic Components**	**BTI Interna Dental Implant System UnicCa®- Prosthetic components (K213106)**	**BTI Interna Narrow Implant System (K211952)**	**Medentika Multi-Unit abutments (K191123)**
Product Classification	Product Code: NHA Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: NHA Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: DZE, NHA Regulation No.: 21 CFR 872.3640, 21 CFR 872.3630 Device Class II	Product Code: NHA Regulation No.: 21 CFR 872.3630 Device Class II
Material	Commercially pure titanium, Grade 4 Ti6Al4V	Commercially pure titanium, Grade 4 Ti6Al4V	Commercially pure titanium, Grade 4. Ti6Al4V	Ti6Al4V
Surface treatment / Anodization	Titanium Nitride (TiN) DLC (screw)	Titanium Nitride (TiN) DLC (screw)	Titanium Nitride (TiN) DLC (screw)	(None) Not specified in the summary
Restoration	Single and Multi-unit	Single and Multi-unit	Single and Multi-unit	Multi-unit
Abutment fixation	Screw retained	Screw retained	Screw retained	Screw retained
Abutment / Implant Connection	Internal Non-Engaging	Internal Engaging and Non Engaging	Internal Engaging and Non Engaging	Engaging and Non Engaging
Compatible Implant Platform	Interna®Narrow Ø=3.5mm Interna®Universal and Universal Plus Ø=4.1mm	Interna®Universal and Universal Plus Ø=4.1mm Interna®Wide Ø=5.5mm	Interna®Narrow Ø=3.5mm	(See above)
Gingival height (mm)	0.5 - 5.0	1.0 - 4.0 Square Abutments: from 0.5	Transepithelials: 1.0 - 4.0 Square Abutments: from 0.5 mm	0.6 - 5.5
Abutment angulation	0°, 17º, 30º	0°	0°	0º, 17º, 30º
Prosthetic Ø (mm)	3.5, 5.0, 5.5	5.5	3.5, 4.1	(Not known)
Supplied Sterile	Yes	Yes	Yes	Yes
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
SAL	1×10^{-6}	1×10^{-6}	1×10^{-6}	1×10^{-6}
Packaging	Thermoform tray with peel top lid (PETG + TYVEK)	Thermoform tray with peel top lid (PETG + TYVEK)	Thermoform tray with peel top lid (PETG + TYVEK)	Medical grade polyethylene blister with a sealing lid
Shelf file	5 years	5 years	5 years	(Not known)

Table 5-7. Aesthetic Interfaces. Substantial Equivalence – Technological characteristics comparison.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE	REFERENCE DEVICE
Name	**BTI Interna Prosthetic Components**	**BTI Interna Dental Implant System UnicCa - Prosthetic Components (K213106)**	**BTI Dental Implant System UnicCa® – Aesthetic Post Abutments (K231827)**	**Dynamic Ti Base (K212108)**
Product Classification	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II
Material	Commercially pure titanium, Grade 4 Zirconia, ISO 13356	Commercially pure titanium, Grade 4	Commercially pure titanium, Grade 4 Zirconia, ISO 13356	Titanium alloy (Ti6Al4V) Zirconia, ISO 13356
Surface treatment / Anodization	Titanium Nitride (TiN)	Titanium Nitride (TiN)	Titanium Nitride (TiN)	Anodization
Restoration	Single and Multiple	Single and Multiple	Single and Multiple	Single and Multiple
Abutment fixation	Screw retained	Screw retained	Screw retained	Screw retained
Abutment Connection	Internal Engaging and Non Engaging	Internal Engaging and Non Engaging	Internal Engaging and Non Engaging	Internal Engaging and Non Engaging
Height (mm)	4 – 6.5	3.5, 4.2	3.5, 4.2, 6.5	(maximum height) / (cutout height): 4.0 / 2.3 mm 9.0 / 3.5 mm (shortable up to 4 mm for single unit)
Prosthetic Ø (mm)	3.5 – 6.5	5.5, 6.5	3.5 – 6.5	(prosthetic platform diameter): 4.1, 4.3, 4.75, 5.25
Abutment angulation	0º	0º	0º	0º
Supplied Sterile	No	Yes	No	No
Sterilization	To be sterilized by the end user by moist heat	Gamma irradiation	To be sterilized by the end user by moist heat	To be sterilized by the end user by moist heat
Packaging	Thermoform tray with peel top lid (PETG + TYVEK)	Thermoform tray with peel top lid (PETG + TYVEK)	Thermosealed bag	Unknown

Table 5-8. Screws. Substantial Equivalence – Technological characteristics comparison.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	REFERENCE DEVICE
Name	**BTI Interna Prosthetic Components**	**BTI Interna Dental Implant System UnicCa - Prosthetic Components (K213106)**	**BTI Interna Narrow Implant System (K211952)**
Product Classification	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: NHA Abutment, Implant, Dental, Endosseous Regulation No.: 21 CFR 872.3630 Device Class II	Product Code: DZE, NHA Regulation No.: 21 CFR 872.3640, 21 CFR 872.3630 Device Class II
Material	Ti6Al4V	Ti6Al4V	Ti6Al4V
Surface treatment/ Anodization	Color anodization DLC coating	Color anodization DLC coating	Color anodization (selected references) DLC coating
Compatible Implant Platform	Interna®Narrow Ø=3.5mm Interna®Universal and Universal Plus Ø=4.1mm	Interna®Universal and Universal Plus Ø=4.1mm Interna®Wide Ø=5.5mm	Interna®Narrow Ø=3.5mm Interna®Universal Plus Ø=4.1mm
Supplied Sterile	No	Yes	No
Sterilization	To be sterilized by the end user by moist heat	Gamma irradiation	To be sterilized by the end user by moist heat
Packaging	Thermosealed plastic bag	Thermoform tray with peel top lid (PETG + TYVEK)	Thermosealed plastic bag