October 10, 2024

B.T.I. Biotechnology Institute, S.L.
℅ Kevin Thomas
VP & Director of Regulatory Affairs
PaxMed International, LLC
12264 El Camino Real
Suite 400
San Diego, California 92130

Re: K240262
Trade/Device Name: BTI Interna 3.0 Dental Implant System UnicCa®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 30, 2024
Received: September 18, 2024

Dear Kevin Thomas:

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

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

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

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

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

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

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

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sherrill Lathrop Blitzer

for Andrew 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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240262

Device Name

BTI Interna 3.0 Dental Implant System UnicCa®

Indications for Use *(Describe)*

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.

INTERNA 3.0 UnicCa® implants with a diameter of 3.3 mm are only intended 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.

INTERNA 3.0 UnicCa® implants with a diameter of 3.0 mm are only intended for replacement of maxillary lateral incisors and mandibular incisors, and are only intended for delayed loading.

INTERNA 3.0 UnicCa® implants with a diameter of 2.5 mm are only indicated for missing mandibular central and lateral incisors, and are only intended for delayed loading.

All digitally designed zirconia components 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.

510(k) Summary
K240262
B.T.I. Biotechnology Institute, S.L.
BTI Interna 3.0 Dental Implant System UnicCa®

October 10, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	B.T.I. Biotechnology Institute, S.L. Leonardo Da Vinci 14 Miñano, Álava, 01510 Spain
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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	BTI Interna 3.0 Dental Implant System UnicCa®
Common Name	Dental implants and abutments
Regulation Number	21 CFR 872.3640
Regulation Name	Endosseous dental implant
Regulatory Class	Class II
Product Code	DZE
Secondary Product Code	NHA
Classification Panel	Dental
Reviewing Office	Office of Health Technology 1 (Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices)
Reviewing Division	Division of Dental and ENT Devices

PREDICATE DEVICE INFORMATION

Primary Predicate Device
K231827, BTI Dental Implant System UnicCa® - Aesthetic Post Abutments, B.T.I. Biotechnology Institute, S.L.

Reference Devices
K211952, BTI Interna Narrow/Plus Dental Implant System UnicCa®, B.T.I. Biotechnology Institute, S.L.
K150537, MiNi Internal Implant System, MegaGen Implant Co., Ltd.
K122171, MS SA Implant System, OSSTEM Implant Company, Limited
K053355, BTI Interna Dental Implant System, B.T.I. Biotechnology Institute, S.L.

INDICATIONS FOR USE STATEMENT

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.
INTERNA 3.0 UnicCa® implants with a diameter of 3.3 mm are only intended 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.
INTERNA 3.0 UnicCa® implants with a diameter of 3.0 mm are only intended for replacement of maxillary lateral incisors and mandibular incisors, and are only intended for delayed loading.
INTERNA 3.0 UnicCa® implants with a diameter of 2.5 mm are only indicated for missing mandibular central and lateral incisors, and are only intended for delayed loading.
All digitally designed zirconia components for use with Aesthetic Post Abutments are to be sent to a BTI validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to add components to the B.T.I. Biotechnology Institute, S.L. product line of endosseous dental implants, abutments, and prosthetic components. Specifically this submission seeks marketing clearance for dental implants with body diameters of 2.5 mm, 3.0 mm, and 3.3 mm, various compatible conventional abutments, and two-piece abutments to be used with a zirconia superstructure fabricated using CAD-CAM technology.

The subject device Interna 3.0 implants have an internal hexolobular connection and a platform diameter of 3.0 mm. The implants are provided in body diameters of 2.5 mm, 3.0 mm, and 3.3 mm. Each body diameter is provided in overall lengths of 8.5 mm, 10 mm, 11.5 mm, and 13 mm. The subject implants are manufactured from unalloyed titanium (conforming to ASTM F67 and ISO 5832-2), and the endosseous surface has the UniCa® surface treatment that improves the hydrophilicity of the implant.

The subject device abutments are provided in various designs including Healing Abutments, Healing Screws, Temporary Titanium Abutments, Definitive Titanium Abutments, Square Abutments (Ti-Bases), Transepithelial Abutments (Single-unit and Multi-unit, with corresponding screws), and Aesthetic Interfaces for Transepithelial Abutments. The Temporary Titanium Abutments and Definitive Titanium Abutments are provided straight (0°) only and are not to be customized to create an angled abutment or to correct for angulation.

The subject Square Abutments are two-piece abutments consisting of titanium bases combined with ceramic superstructures, to be attached directly to the Interna 3.0 implants to support single-unit or multi-unit restorations. The Square Abutments are provided in gingival heights ranging from 0.5 mm to 3 mm, with a titanium base platform diameter ranging from 3.76 mm to 3.95 mm. The titanium base post height (length above the gingival height) either is 3.5 mm, or in versions with an angled screw access channel, 6.5 mm with a cut-down post height of 2.1 mm, 3 mm, or 3.5 mm. The post of all titanium base versions includes an anti-rotation design to prevent rotation of the superstructure or hybrid crown. The abutments are used with cemented and screw-retained restorations. The fabrication of the top-half of the abutment by conventional workflow was cleared in K211952, and a workflow using CAD-CAM technology to design and fabricate a superstructure or hybrid crown-abutment was cleared in K231827. The ceramic material to be used will be zirconia conforming to ISO 13356. All fabrication of the patient specific superstructures for use with the Square Abutments will be done at a BTI validated milling center. All superstructures will be bonded to the abutment using Multilink Hybrid Abutment Cement (Ivoclar Vivadent AG), cleared in K130436.

The design parameters for the CAD-CAM fabrication of the patient-specific superstructures for use with the Square Abutments are:

minimum wall thickness – 0.4 mm
minimum post height for single-unit restoration (post height is the length above the gingival height) – 4.0 mm
maximum gingival height – 6 mm
minimum gingival height – 0.0 mm in the superstructure
(all Square Abutments have a minimum gingival height of 0.5 mm)
maximum angle – 0°, straight only.

Transepithelial Abutments are for supporting single-unit or multi-unit, temporary or definitive, restorations on the Interna 3.0 implants. Transepithelial Abutments are provided to fit implants with a body diameter of 2.5 mm, and to fit body diameters of either 3.0 mm or 3.3 mm. Transepithelial Abutments are provided in a variety of gingival heights ranging from 0.5 mm to 5 mm. Transepithelial Abutments are used with previously cleared BTI retention screws, temporary cylinders, aesthetic interfaces, and the subject device Aesthetic Interfaces for Transepithelial Abutments.

The subject Aesthetic Interfaces for Transepithelial Abutments are two-piece abutments consisting of titanium bases combined with ceramic superstructures, used to support single or multi-unit definitive prosthetic restorations. Aesthetic Interfaces for Transepithelial Abutments are provided in gingival heights of 0.5 mm to 1.05 mm, titanium base diameters ranging from 3.5 mm to 6.5 mm, and titanium base post heights (length above the gingival height) ranging from 5.45 mm to 6.5 mm. Aesthetic Interfaces for Transepithelials are provided in two configurations, Straight and Expanded; the Expanded configurations have a larger titanium base platform diameter than the Straight configurations with the same platform diameter. The titanium base platform diameters range from 3.5 mm to 6.5 mm and all designs include anti-rotation indexes to prevent rotation of the superstructure or hybrid crown. The fabrication of the top-half of the abutment by conventional workflow was cleared in K211952 and a workflow using CAD-CAM technology to design and fabricate a superstructure or hybrid crown-abutment was cleared in K231827. The ceramic material to be used will be zirconia conforming to ISO 13356. All fabrication of the patient specific superstructures will be done at BTI validated milling center. All superstructures will be bonded to the abutment using Multilink Hybrid Abutment Cement (Ivoclar Vivadent AG), cleared in K130436.

The design parameters for the CAD-CAM fabrication of the patient-specific superstructures for use with the Aesthetic Interfaces for Transepithelial Abutments are:

minimum wall thickness – 0.4 mm
minimum post height for single-unit restoration (post height is the length above the gingival height) – 4 mm
maximum gingival height – 6 mm
minimum gingival height – 0.0 mm in the superstructure
(all Aesthetic Interfaces have a minimum gingival height of 0.5 mm)
maximum angle – 0°, straight only.

All subject device abutments are manufactured from unalloyed titanium conforming to ASTM F67 and ISO 5832-2, and zirconia confirming to ISO 13356. Selected abutments are provided with a Titanium Nitride (TiN) coating to enhance the aesthetic appearance of the device. Subject device abutments used with screws previously cleared in K211952 and K053355. The screws that are part of the Transepithelial Abutment assemblies are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and ISO 5832-3, The screws have a diamond-like carbon (DLC) coating that is identical to the DLC coating on screws cleared in K211952.

Subject device components provided sterile by gamma irradiation include the Interna 3.0 Implants, Healing Abutments, Healing Screws, and Transepithelial Abutments. Components provided non-sterile for end-user moist heat sterilization include the Temporary Titanium Abutments, Definitive Titanium Abutments, Square Abutments, Aesthetic Interfaces for Transepithelial Abutments, and retention screws.

PERFORMANCE DATA

Non-clinical data submitted or referenced to demonstrate substantial equivalence included:

- provided in this submission was a non-clinical worst-case MRI review 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, and the 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;
- provided in this submission to demonstrate substantial equivalence were measurements of the total surface area, the surface area after simulated 3 mm of bone loss, and the initial bone-to-implant contact area for the subject implants with diameters of 2.5 mm and 3.0 mm compared to the same areas for implants with diameters of 2.5 mm and 3.0 mm from the reference devices K150537 and K122171;
- referenced from K231827 was moist heat sterilization validation for the subject devices 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;
- referenced from K211952 was gamma sterilization to a sterility assurance level of 10^{-6} by selecting and substantiating a 25 kGy dose using method VD_{max}^{25}, according to ISO 11137-1 and ISO 11137-2;
- referenced from K211952 were sterile barrier shelf life data;
- referenced from K231827 and K211952 were biocompatibility data for the subject device materials (unalloyed titanium conforming to ASTM F67 and ISO 5832-2, and zirconia conforming to ISO 13356), the abutment TiN surface treatment, and the implant UniCa® surface treatment.

No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided at the end of this summary is a table comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device K231827, and the reference device K211952, K150537, and K122171.

The primary predicate device K231827 is in support of substantial equivalence for the similar Indications for Use statement, abutment designs, materials, manufacturing, and sterilization. The reference device K211952 is in support of substantial equivalence for the similar Indications for Use statement, implant designs, abutment designs, materials, manufacturing, and sterilization. The reference devices K150537 and K122171 are for the implant designs (sizes) and for comparison in the performance testing (described below).

The Indications for Use Statement (IFUS) for the subject device includes language concerning the implants that is identical to that in the reference device K211952. The indications language for the subject INTERNA 3.0 UnicCa® implants with a diameter of 3.3 mm is the same as for the Tiny® 3.0 UnicCa® implants in the reference device K211952. Similarly, the indications language for the subject INTERNA 3.0 UnicCa® implants with a diameter of 3.0 mm is the same as for the MiNi implants (3.0 mm diameter) in the reference device K150537, and the indications language for the subject INTERNA 3.0 UnicCa® implants with a diameter of 2.5 mm is the same as for the MS SA implants (2.5 mm diameter) in the reference device K122171. The IFUS for the subject device also includes language stating that digitally designed components are to be manufactured at a validated milling center; this language is identical to that in the primary predicate device K231827.

Differences between the IFUS for the subject device and the reference device K211952 includes language related to the sizes and uses of implants in the respective submissions. The IFUS for K211952 does not include language

regarding the validated milling centers because K211952 does not include a CAD-CAM workflow. The IFUS for the primary predicate device K231827 does not include language regarding dental implants because the K231827 submission does not include implants. Differences between the IFUS for the subject device and the reference devices K150537 and K122171 include the reference devices do not include language regarding validated milling center, and the language in K122171 regarding the MIS SA (denture) implant. The minor differences in the IFUS for the subject device, the primary predicate K231827, and the reference devices do not affect substantial equivalence because all devices have the same intended use for functional and esthetic rehabilitation of the edentulous mandible or maxilla.

The subject device implants are compatible with the subject device abutments, and with abutment screws cleared previously in the reference device K211952 and the sponsor's K053355 submission.

The subject device dental implants have a similar design and abutment connection as the implants cleared in the reference device K211952. The subject device implants and the implants cleared in K211952 are manufactured from the same material, have the same endosseous surface treatment, and are sterilized by the same method (gamma irradiation). The subject body diameter sizes are substantially equivalent to those of the reference devices K150537 and K122171.

The subject device abutments and the abutments cleared in K231827 and K211952 have similar designs, are manufactured from the same material, surface treatment (TiN), and are provided either sterilized by the same method (gamma irradiation), or are to be end-user sterilized by the same method (moist heat). The subject abutments and the abutments cleared in K231827 and K211952 have similar designs for single-unit and multi-unit restorations (engaging and non-engaging connections), and similar ranges of prosthetic platform diameter and gingival heights.

The subject device Square Abutments and Aesthetic Interfaces for Transepithelial Abutments are the apical part of a two-piece abutment and require a superstructure to complete the abutment. The design limits for the subject device digitally designed superstructures are similar to those of the primary predicate device K231827. All digitally designed superstructures are to be manufactured at a validated milling center; this requirement is the same as that of the primary predicate device K231827.

The subject device abutments are manufactured from unalloyed titanium conforming to ASTM F67 and ISO 5832-2. Selected subject device abutments are provided with a Titanium Nitride (TiN) coating to enhance the aesthetic appearance of the device. This material and TiN coating are identical to the material and coating for the abutments cleared in K231827 and K211952. The screws that are part of the Transepithelial Abutment assemblies are manufactured from Ti-6Al-4V alloy conforming to ASTM F136 and ISO 5832-3. The screws have a diamond-like carbon (DLC) coating that is identical to the DLC coating on screws cleared in K211952.

All superstructures for use with the subject abutments will be manufactured from zirconia conforming to ISO 13356. All superstructures will be bonded to the abutment using Multilink Hybrid Abutment Cement (Ivoclar Vivadent AG, cleared in K130436). This zirconia material and bonding cement are the same as those required for the primary predicate device K231827.

To demonstrate substantial equivalence of the subject device implant body diameters less than 3.25 mm to the reference devices K150537 and K122171, comparative surface area analysis was performed. The comparisons performed were: the surface area for the entire implanted length of the device; the surface area for the implanted length of the device, after simulating a possible 3 mm of bone loss; and the area of bone to implant contact, immediately after placement. For each of the conditions investigated, the surface area of the subject devices compared favorably with the surface areas of the corresponding reference devices.

CONCLUSION

The subject device, the primary predicate device, and the reference devices have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate device, and the reference devices encompass the same range of physical dimensions, are packaged in similar materials, and

are to be sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

The basis for the belief of B.T.I. Biotechnology Institute, S.L. that the subject device is substantially equivalent to the predicate devices is summarized in the following *Table of Substantial Equivalence*.

Table of Substantial Equivalence

Comparisons	Subject Device **K240262** **BTI Interna 3.0 Dental Implant System UnicCa®** **B.T.I. Biotechnology Institute, S.L.**	Predicate Device **K231827** **BTI Dental Implant System UnicCa® – Aesthetic Post Abutments** **B.T.I. Biotechnology Institute, S.L.**	Reference Device **K211952** **BTI Interna Narrow/Plus Dental Implant System UnicCa®** **B.T.I. Biotechnology Institute, S.L.**	Reference Device **K150537** **MiNi Internal Implant System** **MegaGen Implant Co., Ltd.**	Reference Device **K122171** **MS SA Implant System** **OSSTEM Implant Company, Limited**
Indications for Use Statement (IFUS)	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. INTERNA 3.0 UnicCa® implants with a diameter of 3.3 mm are only intended 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. INTERNA 3.0 UnicCa® implants with a diameter of 3.0 mm are only intended for replacement of maxillary lateral incisors and mandibular incisors, and are only intended for delayed loading. INTERNA 3.0 UnicCa® implants with a diameter of 2.5 mm are only indicated for missing mandibular central and lateral incisors, and are only intended for delayed loading. All digitally designed zirconia components for use with Aesthetic Post Abutments are to be sent to a BTI validated milling center for manufacture.	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.	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 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.	The MiNi Internal Implant System is intended for two-stage surgical procedures in the following situations and with the following clinical protocols: - The intended use for the 3.0 mm diameter MiNi implant is limited to the replacement of maxillary lateral incisors and mandibular incisors. - Immediate placement in extraction sites and in situations with a partially or completely healed alveolar ridge. - It is intended for delayed loading.	The MIS SA Implant (Denture) is intended to be placed in the bane of the upper or lower jaw arches to provide support of the prosthetic devices to restore the patients chewing function, including the denture stabilization. The MS SA Implant (Denture) is intended for single use only. It is intended for delayed loading. The MS SA Implant (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The MIS SA Implant (Narrow Ridge) is intended for single use only. It is intended for delayed loading.
Reason for Predicate / Reference Device	Not applicable	IFUS (for Aesthetic Post Abutments); abutment designs; materials; manufacturing; sterilization	IFUS (for Ø 3.3 mm implants); implant designs; abutment designs; materials; manufacturing; sterilization; shelf life	IFUS (for Ø 3.0 mm implants); implant designs	IFUS (for Ø 2.5 mm implants); implant designs
Product Codes	DZE, NHA	NHA	DZE, NHA	DZE, NHA	DZE
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla	Functional and esthetic rehabilitation of the edentulous mandible or maxilla
Abutment Designs	Healing Abutments, Healing Screws Temporary Titanium Straight Abutments Definitive Titanium Straight Abutments Square Abutments Transepithelial Abutments, Single-unit and Multi-unit Aesthetic Interfaces for Transepithelial Abutments	Square Aesthetic Abutments Aesthetic Interfaces for Transepithelials	Various designs including: Healing Abutments, Closure (Healing) Screws Temporary Titanium Abutments Square Aesthetic Abutments Transepithelial Abutments, Single-unit and Multi-unit Aesthetic Interfaces		
Restoration types	Single-unit and Multi-unit	Single-unit and Multi-unit	Single-unit and Multi-unit		
Compatible Implant Connections	Internal	Internal	Internal		
Compatible Implants and Implant platform diameter	Subject device Interna 3.0, body diameters 2.5 mm, 3.0 mm, 3.3 mm All with platform 3.0 mm	Interna Narrow, 3.5 mm Interna Universal and Interna Universal Plus, 4.1 mm Interna Wide, 5.5 mm	Interna Narrow, 3.5 mm Interna Universal Plus, 4.1 mm		
Titanium Platform diameter	3.4 mm – 4.5 mm	Square Aesthetic Abutments, 4 mm – 5.9 mm Aesthetic Interfaces for Transepithelials, 3.5 mm – 6.5 mm	3.5 mm – 5.1 mm		
Gingival Height in Abutment	0.5 mm – 4.0 mm	Square Aesthetic Abutments, 0.55 mm – 3.5 mm Aesthetic Interfaces for Transepithelials, 0.3 mm – 1.1 mm	0.5 mm – 4.0 mm		
Titanium Post Height (length above the gingival height)	3.5 mm – 6.5 mm Angled screw channel design: 6.5 mm max / 2.1 mm, 3mm, or 3.5 mm min	3.5 mm – 6.5 mm	*Not stated in 510(k) Summary*		

Comparisons	Subject Device **K240262** **BTI Interna 3.0 Dental Implant System UnicCa®** **B.T.I. Biotechnology Institute, S.L.**	Predicate Device **K231827** **BTI Dental Implant System UnicCa® – Aesthetic Post Abutments** **B.T.I. Biotechnology Institute, S.L.**	Reference Device **K211952** **BTI Interna Narrow/Plus Dental Implant System UnicCa®** **B.T.I. Biotechnology Institute, S.L.**	Reference Device **K150537** **MiNi Internal Implant System** **MegaGen Implant Co., Ltd.**	Reference Device **K122171** **MS SA Implant System** **OSSTEM Implant Company, Limited**
Superstructure design limits					
Minimum wall thickness	0.4 mm	0.22 mm – 0.55 mm			
Minimum post height for single-unit restoration	4.0 mm	4.0 mm – 4.2 mm			
Maximum gingival height	6.0 mm	As required			
Minimum gingival height	0 mm (in the superstructure)	0.3 mm – 0.5 mm (in the abutment base)			
Maximum angle	0°, straight only	0°, straight only			
Abutment Materials					
Abutment Base	Unalloyed titanium, ASTM F67 / ISO 5832-2	Unalloyed titanium, ASTM F67 / ISO 5832-2	Unalloyed titanium, ASTM F67 / ISO 5832-2		
Abutment Base coating	Titanium nitride (TiN)	Titanium nitride (TiN)	Titanium nitride (TiN)		
Superstructure, CAD-CAM workflow	Zirconia, ISO 13356	Zirconia, ISO 13356			
Cement, CAD-CAM workflow	Multilink Hybrid Abutment Cement (Ivoclar Vivadent AG, cleared in K130436)	Multilink Hybrid Abutment Cement (Ivoclar Vivadent AG, cleared in K130436)			
Transepithelial Abutment Screws	Ti-6Al-4V alloy ASTM F136 / ISO 5832-3, with DLC coating		Ti-6Al-4V alloy ASTM F136 / ISO 5832-3, with DLC coating		
Implant Designs					
Body diameter	2.5 mm, 3.0 mm, 3.3 mm		Interna Narrow, 3.3 mm – 4.75 mm Interna Universal Plus, 6.0 mm	3.0 mm, 3.4 mm	2.5 mm, 2.9 mm
Platform diameter	All body diameters, platform 3.0 mm		Interna Narrow, 3.5 mm Interna Universal Plus, 4.1 mm	*Not stated in 510(k) Summary*	Not applicable (1-piece design)
Length	All body diameters, 8.5, 10.0, 11.5, 13.0 mm		Interna Narrow, 5.5 mm – 15 mm Interna Universal Plus, 7.5 mm – 11.5 mm	8.0, 9.5, 11.0, 12.5, 14.5 mm	8.5, 10.0, 11.5, 13.0 mm (threaded length)
Material	Unalloyed titanium, ASTM F67 / ISO 5832-2		Unalloyed titanium, ASTM F67 / ISO 5832-2	Unalloyed titanium, ASTM F67, Grade 4	Ti-6Al-4V alloy, ASTM F136
Endosseous surface treatment	Calcium surface treatment		Calcium surface treatment	SLA (Sand-blasted, Large grit, Acid-etched)	Sand-blasted, Acid-etched (SA)
How Provided					
Abutments	Sterile by gamma irradiation, and Non-sterile, requires moist heat sterilization	Non-sterile, requires moist heat sterilization	Sterile by gamma irradiation, and Non-sterile, requires moist heat sterilization		
Implants	Sterile by gamma irradiation		Sterile by gamma irradiation	Sterile by gamma irradiation	Sterile by irradiation
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use