9-15-23

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

Re: K231827
Trade/Device Name: BTI Dental Implant System UnicCa® - Aesthetic Post Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 21, 2023
Received: June 21, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231827

Device Name

BTI Dental Implant System UnicCa® – Aesthetic Post Abutments

Indications for Use *(Describe)*

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.

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
K231827
B.T.I. Biotechnology Institute, S.L.
BTI Dental Implant System UnicCa® – Aesthetic Post Abutments

September 11, 2023

ADMINISTRATIVE INFORMATION

Manufacturer Name	B.T.I. Biotechnology Institute, S.L. Leonardo Da Vinci 14 Miñano, Álava, 01510 Spain
Telephone	+34 945 297 030
Fax	+34 945 297 031
Official Contact	José Ramón Rivero, Technical Manager
Representative/Consultant	Kevin A. Thomas, PhD Floyd G. Larson, MS, MBA PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone +1 858-792-1235 Fax +1 858-792-1236 Email kthomas@paxmed.com flarson@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	BTI Dental Implant System UnicCa® – Aesthetic Post Abutments
Common Name	Dental implant abutment
Regulation Number	21 CFR 872.3630
Regulation Name	Endosseous dental implant abutment
Regulatory Class	Class II
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
K213106, BTI Interna Dental Implant System UnicCa® – Prosthetic Components, 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.
K212628, DESS Dental Implants, Terrats Medical SL

INDICATIONS FOR USE STATEMENT

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.

SUBJECT DEVICE DESCRIPTION

The purpose of this submission is to obtain marketing clearance for the subject device abutments, Square Aesthetic Abutments and Aesthetic Interfaces for Transepithelials, as part of a two-piece abutment with a zirconia superstructure fabricated using CAD-CAM technology.

The subject Square Aesthetic abutments are stock manufactured abutments, to be attached directly to BTI dental implants with the Interna implant connection (Narrow, Universal, Universal Plus and Wide platforms), to hold single or multiple restorations. The Square Aesthetic abutments are compatible with BTI implants previously cleared in K211952, K202825, K173257, and K151391. The subject Square Aesthetic abutments are provided in a variety of gingival heights ranging from 0.5 mm to 3.5 mm, with a prosthetic platform diameter ranging from 4.0 mm to 5.9 mm, and a prosthetic post height of 3.5 mm. All versions include anti-rotation indexes to prevent crown or bridge rotation. Engaging and non-engaging designs are available for single and multiple restorations, respectively. The abutments are used with cemented and screw-retained restorations.

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

- minimum wall thickness – 0.45 mm
- minimum post height for single-unit restoration – 4.2 mm
- maximum gingival height – 6.0 mm
- minimum gingival height – 0 mm in the zirconia superstructure
- maximum angle – 0°, straight only.

The subject Aesthetic Interfaces for Transepithelials are stock manufactured abutments, used to support single or multi-unit definitive prosthetic restorations over BTI Transepithelial Abutments (Unit and Multi-im, respectively). The compatible Transepithelial Abutments were previously cleared in K213106 and K211952, and the Transepithelial Abutments are compatible with the BTI Interna connection implants (Narrow, Universal, Universal Plus and Wide platforms), previously cleared in K211952, K202825, K173257, and K151391. The previously cleared Transepithelial Abutments have a minimum gingival height of 1.0 mm and the Aesthetic Interfaces for Transepithelials have a minimum gingival height of 0.3 mm; when used together (as required) the minimum gingival height is 1.3 mm. The Aesthetic Interfaces for Transepithelials are provided in a range of prosthetic diameters from 3.5 mm to 6.5 mm, with a range of post heights from 3.5 mm to 6.5 mm. The Aesthetic Interfaces for Transepithelials are provided in two configurations, Straight and Expanded. The Expanded configurations have a larger prosthetic platform diameter than the Straight configurations with the same platform diameter. Overall, the prosthetic platform diameters range from 3.5 mm to 6.5 mm.

The design parameters for the CAD-CAM fabrication of the patient-specific superstructures for use with the Aesthetic Interfaces for Transepithelials vary for the minimum wall thickness and prosthetic post height depending on the design of the Aesthetic Interface and the corresponding Transepithelial Abutments. The overall design parameters for the CAD-CAM fabrication of the patient-specific superstructures for use with the Aesthetic Interfaces for Transepithelials are:

- minimum wall thickness – 0.4 mm
- minimum post height for single-unit restoration – 4 mm
- maximum gingival height – 6.0 mm
- minimum gingival height – 0 mm in the zirconia superstructure
- maximum angle – 0°, straight only.

All zirconia superstructures for use with the subject device will be made at a B.T.I. Biotechnology Institute, S.L. validated milling center under FDA quality system regulations, and the material will conform to ISO 13356. All superstructures will be bonded to the abutment using Multilink Hybrid Abutment Cement (Ivoclar Vivadent AG, cleared in K130436).

All subject device components are manufactured from unalloyed titanium conforming to ASTM F67 and ISO 5832-2 and are provided with a Titanium Nitride (TiN) coating to enhance the aesthetic appearance of the device. All subject device components are used with abutment and prosthetic screws previously cleared in K213106, K211952, and K053355.

PERFORMANCE DATA

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

- provided in this submission was non-clinical worst-case MRI review was performed 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.
- provided in this submission 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, and ANSI/AAMI/ISO 14937;
- provided in this submission was biocompatibility testing according to ISO 10993-5 (cytotoxicity) for the final abutment (unalloyed titanium base and bonded zirconia superstructure).

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, and the reference devices.

The primary predicate device K213106 is in support of substantial equivalence for the abutment designs, materials, manufacturing, and compatible implants. The reference device K211952 is for the Indications for Use, abutment designs, materials, manufacturing, compatible implants, and sterilization. The reference device K212628 is for the Indications for Use for CAD-CAM workflow, abutment designs, superstructure design and materials, and bonding cement. Minor differences in the IFUS for the subject device, the primary predicate device, 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 components are compatible with the same BTI Interna dental implants as the primary predicate K213106 and reference device K211952. The subject device Square Aesthetic Abutments and Aesthetic Interfaces for Transepithelials are provided in the same designs and materials as these devices in K213106 and K211952 (for use with a conventional workflow). The subject devices have the same designs for single-unit and multi-unit restorations (engaging and non-engaging connections), and the same ranges of prosthetic platform diameter and gingival heights.

The subject device Square Aesthetic Abutments and Aesthetic Interfaces for Transepithelials 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 reference device K212628. The digitally designed superstructures for the subject device are to be manufactured at a validated milling center; this requirement is the same as that of the reference device K212628.

The subject device components are manufactured from the same material (unalloyed titanium conforming to ASTM F67 and ISO 5832-2). All 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 K213106 and 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 (Ivoclar Vivadent AG, cleared in K130436). This zirconia material and bonding cement are the same as those required for the reference device K212628.

The subject device components are provided non-sterile. After fabrication of the zirconia superstructure by the validated milling center and bonding of the superstructure to the abutment, the final device is to be sterilized by moist heat by the end user. This requirement is the same as that of the reference device K212628.

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.

Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	K231827 **BTI Dental Implant System UnicCa® – Aesthetic Post Abutments** **B.T.I. Biotechnology Institute, S.L.**	**K213106** **BTI Interna Dental Implant System UnicCa® – Prosthetic Components** **B.T.I. Biotechnology Institute, S.L.**	**K211952** **BTI Interna Narrow/Plus Dental Implant System UnicCa®** **B.T.I. Biotechnology Institute, S.L.**	**K212628** **DESS Dental Smart Solutions** **Terrats Medical SL**
Indications for Use Statement	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 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.	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.	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 Blanks are to be sent to a Terrats Medical validated milling center for manufacture. *For the complete Indications for Use Statement including the list of compatible implant systems, see the 510(k) Summary for K212628.*
Reason for Predicate Device	Not applicable	IFUS; compatible implants; abutment designs; materials; manufacturing	IFUS; compatible implants; abutment designs; materials; manufacturing; sterilization	IFUS for CAD-CAM workflow; abutment designs; bonding cement
Product Codes	NHA	NHA	DZE, NHA	NHA
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
Abutment Designs				
	Square Aesthetic Abutments Aesthetic Interfaces for Transepithelials	Various abutment designs including Square Aesthetic Abutments Aesthetic Interfaces for Transepithelials	Various abutment designs including Square Aesthetic Abutments Aesthetic Interfaces for Transepithelials	Various abutment designs including multiple Ti Base type abutment designs
Restoration types	Single-unit and Multi-unit	Single-unit and Multi-unit	Single-unit and Multi-unit	Single-unit and Multi-unit
Compatible Implant Connections	Internal	Internal	Internal	Internal, External
Compatible Implants and Implant platform diameter	Interna Narrow, 3.5 mm Interna Universal and Interna Universal Plus, 4.1 mm Interna Wide, 5.5 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	Various implants 3.0 mm – 6.0 mm (for Ti Base type abutments)
Prosthetic Platform diameter	Square Aesthetic Abutments, 4 mm – 5.9 mm Aesthetic Interfaces for Transepithelials, 3.5 mm – 6.5 mm	4.1 mm – 6.5 mm	3.5 mm – 5.1 mm	4.5 mm – 6.5 mm
Gingival Height in Abutment	Square Aesthetic Abutments, 0.5 mm – 3.5 mm Aesthetic Interfaces for Transepithelials, 0.3 mm – 1.1 mm	Up to 4 mm maximum	0.5 mm – 4.0 mm	*Not stated in 510(k) Summary*
Superstructure design limits				
Minimum wall thickness	0.4 mm			0.4 mm – 0.45 mm
Minimum post height for single-unit restoration	4.0 mm – 4.2 mm			4.0 mm – 4.2 mm
Maximum gingival height	6.0 mm			6.0 mm
Minimum gingival height	0 mm – in the zirconia superstructure			0.5 mm
Maximum angle	0°, straight only			0°, straight only

Table of Substantial Equivalence

	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	K231827 **BTI Dental Implant System UnicCa® – Aesthetic Post Abutments** **B.T.I. Biotechnology Institute, S.L.**	**K213106** **BTI Interna Dental Implant System UnicCa® – Prosthetic Components** **B.T.I. Biotechnology Institute, S.L.**	**K211952** **BTI Interna Narrow/Plus Dental Implant System UnicCa®** **B.T.I. Biotechnology Institute, S.L.**	**K212628** **DESS Dental Smart Solutions** **Terrats Medical SL**
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	Ti-6Al-4V alloy, ASTM F136 Co-Cr-Mo alloy, ASTM F1537
Abutment Base coating	Titanium nitride (TiN)	Titanium nitride (TiN)	Titanium nitride (TiN)	None
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)
How Provided				
Abutments	Non-sterile, requires moist heat sterilization	Sterile by gamma irradiation	Sterile by gamma irradiation, and Non-sterile, requires moist heat sterilization	Non-sterile, requires moist heat sterilization
Usage – All Components	Single patient, single use	Single patient, single use	Single patient, single use	Single patient, single use