July 29, 2021

B.T.I. Biotechnology Institute, S.L.
Jose Rivero
Qualified Person
Leonardo da Vinci 14, Parque Tecnologico de Alava
Minano, Alava 01510
SPAIN

Re: K202825
Trade/Device Name: BTI Extra-Short Dental Implant System UnicCa®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: June 25, 2021
Received: July 2, 2021

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 (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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202825

Device Name
BTI Extra-Short 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.

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.

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 – K202825

I. SUBMITTER

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Contact Person: Mr. José Ramón Rivero
Date Prepared: July 29, 2021

II. DEVICE

Name of Device: BTI Extra-Short Dental Implant System UnicCa®
Common or Usual Name: Root-form Endosseous Dental Implant
Classification Name: Endosseous Dental Implant (21 CFR 872.3640)
Regulatory Class: II
Product Code: DZE

III. PREDICATE DEVICE

The primary predicate devices are the BTI Dental Implant System UnicCa® Interna® Implants which were subject of K151391, BTI Dental Implant System UnicCa® (cleared on May 2, 2016).

Additionally, the following reference devices have been identified to bridge the gap in implant dimensions (i.e., for the narrower/shorter implants) that are outside the scope of currently cleared BTI UnicCa® Interna® implants. These reference devices are marketed in dimensions similar to those included in this submission:

- K133049, 3I T3(R) External Hex Dental Implants (Biomet 3I), January 8, 2014.
- K170392, S.I.N. Implant System (S.I.N. – Sistema De Implante Nacional S.A.), December 5, 2017.

IV. DEVICE DESCRIPTION

The BTI Dental Implant System UnicCa® is a self-tapping, threaded, root form dental titanium implant provided with two types of connections; external (i.e., Externa®) and internal (i.e., Interna®), in a variety of platforms and range of diameters (3.0 – 6.0 mm) and lengths (5.5 – 18.0 mm). BTI Dental Implant System UnicCa® features an implant surface treatment that improves the hydrophilicity of the implant.

The purpose of this 510(k) is to allow B.T.I. Biotechnology Institute, S.L. to expand the product offering for the Universal and Universal Plus Interna® implant platforms. Specifically, the currently cleared Universal Interna® implants with diameters ranging from 4.0 to 4.25 mm and the 6.0 mm diameter Universal Plus Interna® implants will be provided in shorter lengths of 5.5 and 6.5 mm. The implants subject of this premarket notification, collectively referred to as *BTI Extra-Short Dental Implant System UnicCa®*, are summarized in **Table 5-1**.

Table 5-1. Overview of **BTI Extra-Short Dental Implant System UnicCa®**, platforms, diameters and lengths subject of this premarket notification:

Connection	Platform	Diameter (mm)	Length (mm)
Interna®	Universal	4.0	5.5
		4.25	5.5
	Universal Plus	6.0	5.5 / 6.5

This submission does not include any new abutments. The subject device is compatible with abutments previously cleared under K053355, K061383, and K070533.

V. INDICATIONS FOR USE

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.

VI. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The *BTI Extra-Short Dental Implant System UnicCa®* have the following similarities to the UnicCa® implants which previously received 510(k) concurrence via K151391:

- have identical indications for use,
- use identical operating principle,
- incorporate identical materials,
- have the identical surface treatment,
- have identical shelf life, and
- are packaged and sterilized using the identical materials and processes.

Table 5-2 represents diameters and lengths of the Interna® connection cleared within K151391 (and K173257 which extended the range of implant sizes) and the dental implants subject of this current Traditional 510(k) submission.

Table 5-2. Range of platform, diameter and lengths of the predicate UnicCa® Interna® implant previously cleared within K151391 and additional size offerings subject of this 510(k) submission (new size offerings subject of this premarket notification identified in bold text).

Connection	Platform	Diameter ⌀ (mm)	Length ↕ (mm)
Interna®	Universal	3.3	8.5 / 10 / 11.5 / 13 / 15
		3.5	7.5 / 8.5 / 10 / 11.5 / 13 / 15
		3.75	7.5 / 8.5 / 10 / 11.5 / 13 / 15
		4.0	**6.5** / 7.5 / 8.5 / 10 / 11.5 / 13 / 15 / 18
		4.25	**6.5** / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
	Universal Plus	4.5	5.5 / 6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
		5.0	5.5 / 6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
		5.5	5.5 / 6.5
		6.0	**5.5 / 6.5**
	Wide	5.0	6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
		5.5	5.5 / 6.5
		6.0	5.5 / 6.5

A comparison of the device features, indications for use, bench testing and other information demonstrate that the *BTI Extra-Short Dental Implant System UnicCa®* is substantially equivalent to the primary predicate device (K151391).

Table 5-3 compares the subject devices with the primary predicate (K151391). To bridge the gap in differences in implant dimensions; i.e., specifically for the implants that have dimensions outside those currently cleared for the UnicCa® product line, BTI has identified reference devices, **Table 5-4,** which have similar dimensions to the narrower and shorter implants proposed as well as similar design and intended use as the implants presented within this submission. The differences in dimensions have been demonstrated to not be unique to the subject device.

Table 5-3. Comparison of the *BTI Extra-Short Dental Implant System UnicCa®* with **primary predicate** BTI Dental Implant System UnicCa® (K151391)

Characteristics	**Subject Device (Current Submission)** **BTI Extra-Short Dental Implant System UnicCa®**	**Primary Predicate** **K151391, BTI Dental Implant System UnicCa®**	**Substantial Equivalence Discussion**
Product Classification	Device Class II Regulation No.:21 CFR 872.3640. Product code: DZE; Endosseous dental implant.	Device Class II Regulation No.:21 CFR 872.3640. Product code: DZE; Endosseous dental implant.	Identical.

Characteristics	Subject Device (Current Submission) BTI Extra-Short Dental Implant System UnicCa®	Primary Predicate K151391, BTI Dental Implant System UnicCa®	Substantial Equivalence Discussion
Indications for use	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.	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.	Identical.
Implant Design/Geometry	Threaded, root form.	Threaded, root form.	Identical.
Material	Commercially pure titanium grade 4.	Commercially pure titanium grade 4.	Identical.

Characteristics		Subject Device (Current Submission)		Primary Predicate		Substantial Equivalence Discussion
		BTI Extra-Short Dental Implant System UnicCa®		K151391, BTI Dental Implant System UnicCa®		
Abutment Compatibility/ Connection		Internal (Interna).		Internal (Interna) and External (Externa).		Identical. Primary predicate also includes implants with External connection.
Dimensions (mm)		Interna	Diameter: 4.0 to 6.0 Lengths: 5.5 and 6.5	Interna	Diameter: 3.3 to 6.0 Lengths: 5.5 to 18.0	Similar. The diameters and lengths in current submission for Interna connection are already encompassed in Primary Predicate.
		Externa	Not applicable.	Externa	Diameter: 3.0 to 5.5 Lengths: 7.0 to 18.0	
Roughness		Neck: Sq[1]= 0.7 ± 0.1 µm; Sdr[2]= 50± 10%		Neck: Sq= 0.7 ± 0.1 µm; Sdr= 50± 10%		Identical.
		Thread: Sq≥ 1.2 µm; Sdr≥ 200%		Thread: Sq≥ 1.2 µm; Sdr≥ 200%		
		Valleys: Sq= 1.0 ± 0.2 µm; Sdr= 85± 15%		Valleys: Sq= 1.0 ± 0.2 µm; Sdr= 85± 15%		
Mechanical properties	**Material (Titanium)**	In compliance with ISO 5832-2 and ASTM F67.		In compliance with ISO 5832-2 and ASTM F67.		Identical.
	Fatigue	Evaluated according to ISO 14801.		Evaluated under ISO 14801.		Identical.
Hydrophilicity		Calcium surface treatment		Calcium surface treatment		Identical.
Supplied Sterile		Yes		Yes		Identical.
Sterilization		Gamma radiation		Gamma Radiation		Identical.
SAL		1×10^{-6}		1×10^{-6}		Identical.
Packaging		Container (vial with clamp)		Container (vial with clamp)		Identical.

[1] Sq: Root Square Mean Roughness.
[2] Sdr= Developped surface.

Characteristics	Subject Device (Current Submission)	Primary Predicate	Substantial Equivalence Discussion
	BTI Extra-Short Dental Implant System UnicCa®	**K151391, BTI Dental Implant System UnicCa®**	
Shelf-Life	Same. 5 years.	5 years.	Identical.

Table 5-4 provides a comparison of the *BTI Extra-Short Dental Implant System UnicCa®* with the selected reference devices**.**

Characteristics	Subject Device (Current Submission)	Reference device	Reference device
	BTI Extra-Short Dental Implant System UnicCa®	**Osseotite BIOMET 3I, LLC (K133049)**	**S.I.N. Dental Implant System (K170392)**
Product Classification	Device Class II Regulation No.:21 CFR 872.3640. Product code: DZE; Endosseous dental implant	Device Class II Regulation No.:21 CFR 872.3640. Product code: DZE; Endosseous dental implant	Device Class II Regulation No.:21 CFR 872.3630 and 872.3640. Product code: DZE; Endosseous dental implant and NHA, Endosseous dental implant abutment

Characteristics	Subject Device (Current Submission)	Reference device	Reference device
	BTI Extra-Short Dental Implant System UnicCa®	**Osseotite BIOMET 3I, LLC (K133049)**	**S.I.N. Dental Implant System (K170392)**
Indications for use	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.	31 T3* Dental Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth restorations and in partially or fully edentulous spans with multiple single teeth utilizing delayed or immediate loading, or as a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures. 3i T3® Dental Implants are intended for immediate function on single tooth arid/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function.	S.I.N. Dental Implant System is intended for placement in the maxillary or mandibular arch to provide support for single-unit or multi-unit restorations. When a one-stage surgical approach is applied, the S.I.N. Dental Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading. Implants with lengths less than 7 mm are intended for delayed loading only.
Material	Titanium CP4	Titanium CP4	Titanium CP4
Connection	Internal	External	Internal

Characteristics	Subject Device (Current Submission)	Reference device	Reference device
	BTI Extra-Short Dental Implant System UnicCa®	**Osseotite BIOMET 3I, LLC (K133049)**	**S.I.N. Dental Implant System (K170392)**
Dimensions (mm)	Diameter: 4.0 -6.0 Lengths: 5.5 and6.5	Diameter: 3.25-6.0 mm Length: 6.5-18.0 mm	Diameter: 2.9 - 6.0 mm Length: 5.0-15.0 mm
Surface	Calcium surface treatment	Discrete crystalline deposition of calcium phosphate surface treatment	Acid-etched HA
Supplied Sterile	Yes	Yes	Yes
Sterilization	Gamma radiation	Irradiation	Radiation sterilization validation according to ISO 11137-1 and 11137-2 and steam sterilization validation according to ISO 17665-1 and ISO 17665-2
Packaging	Container (vial with clamp)	(Not known)	Packaged in a radiation sterilizable package consisting of a primary container, with implant and auxiliary parts, sealed with a peel-off wrapping and grouped in storage packs
Shelf-Life	5 years	(Not known)	(Not known)

VII. NON-CLINICAL TESTING

A series of non-clinical testing has been presented in order to demonstrate that the proposed device is substantially equivalent to the predicate devices. Tests performed are as follows:

- Biocompatibility testing in conformance with ISO 10993-1:2018 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and FDA guidance entitled *Use of International Standard ISO10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" issued on June 16, 2016.* All biological endpoints relative to a long-term implant as identified in the FDA guidance have been addressed with satisfactory results.
- Corrosion Testing, Surface Hydrophilicity and TOF·SIMS Analysis (leveraged from BTI 510(k) K151391).
- Fatigue Testing based on ISO 14801:2016 *Dentistry. Implants. Dynamic fatigue test for endosseous dental implants* and FDA guidance document *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*, issued on May 12, 2004 has been evaluated for the predicate device. Analysis in this submission showed that the subject device did not represent a new worst case for dynamic fatigue testing.
- Comparative area analyses for full external area and for bone resorption of 3 mm have been performed for subject implants and reference device. Additionally, immediate bone to implant contact per surgical protocol for the subject implants and reference device has been assessed. Results showed that subject device is substantially equivalent.
- Sterilization Validation (leveraged from K151391).
- Packaging/Sterile Barrier/Shelf-Life Validation (leveraged from BTI 510(k) K173257).
- Endotoxin Testing: The presence of bacterial endotoxins is addressed according to ANSI/AAMI ST72:2019 *Bacterial endotoxins- Test methods, routine monitoring, and alternatives to batch testing*.

VIII. CLINICAL TESTING

Clinical testing is not required for the dimensional range extension.

IX. CONCLUSIONS

The comparison of similarities and differences between th*e* modified device and the respective predicate device demonstrate that the proposed and predicate device are substantially equivalent.