DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 2, 2016

B.T.I. Biotechnology Institute, S.L.
Ms. Fernanda Olabarria Ros
Regulatory Affairs Manager
Parque Tecnologico De Álava, Leonardo DaVinci 14
01510 Miñano (Álava)
SPAIN

Re: K151391
Trade/Device Name: BTI Dental Implant System UnicCa®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE
Dated: February 19, 2016
Received: February 22, 2016

Dear Ms. Ros:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tina Kiang
-S

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMS No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)
K151391

Device Name
BTI 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 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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# 5.0 510(k) Summary

## I. SUBMITTER

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**Contact Person**: Ms. Fernanda Olabarría
**Date Prepared**: April 20, 2016

## II. DEVICE

**Name of Device**: BTI 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

| Primary Predicate | Reference Predicates |
|---|---|
| K022258;<br>BTI Dental Implant System. | K053355; BTI Interna Dental Implant System.<br>K091387; BTI Dental Implant 5.5 – 6.5.<br>K092112; BTI Dental Implant Tiny® Ø 3.0. |

## IV. DEVICE DESCRIPTION

BTI Dental Implant System UnicCa® is a self-tapping, threaded, root form dental titanium implant. Comprises two types of connections: Externa® and Interna® with a range of diameters (3.0 – 6.0 mm) and lengths (5.5 – 18.0 mm) for various platforms, we refer to **Table 5-1**. BTI Dental Implant System UnicCa® features an implant surface treatment that improves the hydrophilicity of the implant.

**Table 5-1**. Overview of BTI Dental Implant System UnicCa® connections, platforms, diameters and lengths:

| Connection | Platform | Diameter (mm) | Length (mm) |
|---|---|---|---|
| Interna® | 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] |
| | 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] |
| | 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 | [7.5 / 8.5 / 10 / 11.5 / 13 / 15 / 18] |
| | | 4.25 | [7.5 / 8.5 / 10 / 11.5 / 13 / 15] |
| Externa® | Wide | 5.0 | [7.5 / 8.5 / 10 / 11.5 / 13 / 15] |
| | | 5.5 | [7.5 / 8.5 / 10 / 11.5 / 13 / 15] |
| | Universal Plus | 4.5 | [7.5 / 8.5 / 10 / 11.5 / 13 / 15] |
| | | 5.0 | [7.5 / 8.5 / 10 / 11.5 / 13 / 15] |
| | Universal | 3.75 | [7.5 / 8.5 / 10 / 11.5 / 13 / 15] |
| | | 4.0 | [7.5 / 8.5 / 10 / 11.5 / 13 / 15 / 18] |
| | Tiny® | 3.0 | [11.5 / 13 / 15] |
| | | 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] |

## 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 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. COMPARISON OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject dental implants are identical to the currently marketed BTI Dental Implant Systems in indications for use, materials and design.

The BTI Dental Implant System UnicCa® is manufactured using the same procedures and processes as currently utilized for the predicate BTI Dental Implants, with exception that an additional manufacturing step has been added which consists of applying a soluble calcium chloride salt which is deposited at the outermost part of the surface of the implants. The predicate implant surface is known as Optima®, the implant with surface treatment is referred to as UnicCa®. This treatment enhances hydrophilic profile of the implant, easing its wetting characteristics to polar liquids.

A comparison of the device features, indications for use, laboratory data and other information demonstrate that the modified BTI Dental Implant System UnicCa® is substantially equivalent to the predicate devices.

In the following pages, a comparison table has been provided, **Table 5-2**.

**Table 5-2.** Comparison of the BTI Dental Implant System UnicCa® with Predicate BTI Dental Implant Systems:

| Characteristics | Current Submission | Primary Predicate | Reference Predicates | | |
|---|---|---|---|---|---|
| | **BTI Dental Implant System UnicCa® (K151391)** | **BTI Dental Implant System (K022258)** | **BTI Dental Implant System (K053355)** | **BTI Dental Implant 5.5-6.5 (K091387)** | **BTI Dental Implant Tiny® (K092112)** |
| **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.<br><br>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.<br>These implants are indicated only for straight abutments and to support permanently fixed restorations. | 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. | 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. | BTI Dental implants 5.5 - 6.5 mm are intended to be used to restore missing teeth in partially or fully edentulous patients and/or for the fixation of overdentures to restore or enhance the chewing capacity of patients. The device should be used in a two-stage surgical procedure. These implants are not indicated for immediate loading. These implants are not indicated to support removable resilient retained restorations or angled abutments. | BTI Dental Implant Tiny® 3.0 are intended to be used to restore missing teeth in partially or fully edentulous patients and/or the fixation of overdentures'to restore or enhance the chewing capacity of patients.<br>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. |

| Characteristics | Current Submission | Primary Predicate | Reference Predicates | | |
|---|---|---|---|---|---|
| | **BTI Dental Implant System UnicCa® (K151391)** | **BTI Dental Implant System (K022258)** | **BTI Dental Implant System (K053355)** | **BTI Dental Implant 5.5-6.5 (K091387)** | **BTI Dental Implant Tiny® (K092112)** |
| | 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 indications for use statement for the BTI Dental Implant System UnicCa® has been written to encompass the indications for use statements provided with the primary predicate system (K022258) and other previously cleared connections, platforms, diameters and lengths acting as a single consolidated system.<br><br>In this sense, no labeling change that affects the indications for use of the device has been implemented. Information relevant to a specific use of an implant included in previously cleared premarket notifications for BTI Dental Implants are carried forward and included within the labeling for the BTI Dental Implant System UnicCa®. The product continues to be specifically indicated for patients undergoing oral implant surgery for the partial or total replacement of teeth in edentulate patients. | | | | |

| Characteristics | Current Submission | | Primary Predicate | Reference Predicates | | |
|---|---|---|---|---|---|---|
| | **BTI Dental Implant System UnicCa® (K151391)** | | **BTI Dental Implant System (K022258)** | **BTI Dental Implant System (K053355)** | **BTI Dental Implant 5.5-6.5 (K091387)** | **BTI Dental Implant Tiny® (K092112)** |
| **Product Classification** | Device Class II<br>Regulation No.:<br>21 CFR 872.3640.<br>Product code: DZE;<br>Endosseous dental implant | | Device Class II<br>Regulation No.:<br>21 CFR 872.3640.<br>Product code: DZE;<br>Endosseous dental implant | Device Class II<br>Regulation No.: 21 CFR 872.3640.<br>Product code: DZE; Endosseous dental implant | | |
| **Implant Design/Geometry** | Threaded, root form | | Threaded, root form | Threaded, root form | | |
| **Material** | Commercially pure titanium grade 4 | | Commercially pure titanium grade 4 | Commercially pure titanium grade 4 | | |
| **Abutment Compatibility/ Connection** | Internal (Interna) and External (Externa) | | External (Externa) | External (Externa) | Internal (Interna) | External (Externa) |
| **Dimensions (mm)** | Interna | Diameter: 3.3 to 6.0<br>Lengths:<br>5.5 to 18.0 | Diameter:<br>3.3 to 5.5<br>Length:<br>7.0 to 18.0 | Diameter:<br>3.3 to 5.0<br>Length:<br>7.0 to 18.0 | Diameter:<br>4.5 to 6.0<br>Lengths:<br>5.5 to 6.5 | Diameter:<br>3.0<br>Lengths:<br>11.5 to 15.0 |
| | Externa | Diameter: 3.0 to 5.5<br>Lengths:<br>7.0 to 18.0 | Diameter:<br>3.3 to 5.5<br>Length:<br>7.0 to 18.0 | Diameter:<br>3.3 to 5.0<br>Length:<br>7.0 to 18.0 | Diameter:<br>4.5 to 6.0<br>Lengths:<br>5.5 to 6.5 | Diameter:<br>3.0<br>Lengths:<br>11.5 to 15.0 |
| **Roughness** | Same | | Neck: Sq[1]= 0.7 ± 0.1 µm; Sdr[2]= 50± 10%<br>Thread: Sq≥ 1.2 µm; Sdr≥ 200% | Same | | |

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

| Characteristics | | Current Submission | Primary Predicate | Reference Predicates | | |
|---|---|---|---|---|---|---|
| | | **BTI Dental Implant System UnicCa® (K151391)** | **BTI Dental Implant System (K022258)** | **BTI Dental Implant System (K053355)** | **BTI Dental Implant 5.5-6.5 (K091387)** | **BTI Dental Implant Tiny® (K092112)** |
| | | | Valleys: Sq= 1.0 ± 0.2 µm; Sdr= 85± 15% | | | |
| **Mechanical Properties** | **Material (Titanium)** | Same; in compliance with ISO 5832-2 and ASTM F67. | Same; in compliance with ISO 5832-2 and ASTM F67. | Same; in compliance with ISO 5832-2 and ASTM F67. | | |
| | **Fatigue** | Equivalent; platform (diameter and length) dependent. | Equivalent; platform (diameter and length) dependent. | Equivalent; platform (diameter and length) dependent. | | |
| **Hydrophilicity** | | Enhanced | - | | | |
| **Supplied Sterile** | | Yes | Yes | Yes | | |
| **Sterilization** | | Gamma Radiation | e- beam | e- beam | | |
| **SAL** | | $1 \times 10^{-6}$ | $1 \times 10^{-6}$ | $1 \times 10^{-6}$ | | |
| **Packaging** | | Unique container (vial with clamp) | Primary (vial+blister) + Secondary (carboard box) | Primary (vial+blister) + Secondary (carboard box) | | |
| **Shelf-Life** | | 5 years (based on accelerated studies, 1 year real time data from on-going stability studies) | 5 years | 5 years | | |

## VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

### *Biocompatibility Testing*

Biocompatibility tests, in conformance with *ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* were performed. Sample preparation for testing was made based on ISO 10993-12:2012.

**Table 5-3**. Biocompatibility Testing List:

| Biocompatibility Testing | | Standard |
|---|---|---|
| Implant | Cytotoxicity Test | ISO 10993-5:2009 |
| | Delayed Hypersensitivity | ISO 10993-10:2010 |
| | Intracutaneous Reactivity | ISO 10993-10:2010 |
| | Acute Systemic Toxicity | ISO 10993-11:2006 |
| Container | Cytotoxicity Test | ISO 10993-5:2009 |
| Solution | Establishment of allowable limits for leachable substances | ISO 10993-17:2002 |

### *Bench Testing*

Bench testing has been performed for those attributes that may be impacted by the modifications made to the subject device which demonstrates that the proposed modified device met the required specifications for complete design verification tests, which included: Fatigue Testing based on UNE-EN-ISO 14801:2008 (*Dentistry. Implants. Dynamic fatigue test for endosseous dental implants; ISO 14801:2007*), Corrosion Testing, Surface Hydrophilicity TOF·SIMS Analysis, Packaging / Shelf-life Validation and Sterilization Evaluations.

Additionally, as a consequence of the modification of the packaging, a new sterilization method by gamma radiation is applied.

Sterilization validation successfully concluded that the gamma irradiation process, when performed per associated process specifications, can reliably sterilize the subject device to a Sterility Assurance Level of $10^{-6}$. Product integrity and characteristics are not affected by sterilization process, supporting the finding of substantial equivalence with primary and reference predicates.

***Clinical Testing***

BTI conducted an observational retrospective study for BTI Dental Implant System UnicCa®The subjects were over 18 years old, were partially or completely edentulous and required treatment with dental implants and were treated with one or more with at least 6 months of follow-up. Patients whose UniCa implants were still not loaded were excluded. 170 patients with 430 BTI UniCA implants were evaluated. The analysis demonstrated rates of 99.5% and 98.8% respectively for implant- and subject-based survival at 6 months post implant insertion. Implant survival was based upon a stable prosthesis without pain, infections, or any pathology and absence of radiopaque images around the implant, loss of implant, fracture, bone loss > 2-3mm, or infection. No complications or adverse events related to the use of BTI UniCa implants were reported. In comparison, commonly observed survival estimates reported in the literature generally range from 90% to 98%.As a consequence, it is considered that BTI Dental Implant System UnicCa® is substantially equivalent to the declared predicate devices.

## VIII. CONCLUSIONS

The results of the clinical and non-clinical testing and comparison of similarities and differences between the modified devices and the respective predicate devices demonstrate that the proposed and predicate devices are substantially equivalent.