DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 8, 2016

Globaldental, Inc.
Ebless V. Baez Alers, DMD
CEO
San Antonio Drama St. 2067
Ponce, PR 00728

Re: K142846
Trade/Device Name: BBX1, BBX2, BBX1MO, BBX1MC
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: July 25, 2016
Received: July 26, 2016

Dear Ebless V. Baez Alers:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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, Ph.D.
Acting 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: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151987

Device Name

BBX1, BBX2, BBX1MO, BBX1MC

Indications for Use *(Describe)*

BBX1, BBX2, BBX1MO,BBX1MC dental implants are intended for immediate loading in the bone of the maxillary or mandibular arch when optimal primary stability is achieved and appropriate occlusal loading. It is intended for use as support of crown bridges and overdentures when a one stage surgical approach is applied. It is intended for the restoration of a patient's chewing function.

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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GLOBALDENTAL INC.

K142846
510(k) Summary

ADMINISTRATIVE INFORMATION

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Date Prepared: September 8, 2016

Proprietary Name: BBX1, BBX2, BBX1MO, BBX1MC

Common Name: Implant, Endosseous, Root Form

Classification Name: Endosseous Dental Implant

Product Code: DZE, NHA

Regulation Number: 21 CFR 872.3640

DEVICE Class: II

Classification Panel: Dental

INTENDED USE

BBX1, BBX2, BBX1MO, BBX1MC dental implants are intended for immediate loading in the bone of the maxillary or mandibular arch when optimal primary stability is achieved and appropriate occlusal loading. It is intended for use as support of crown bridges and overdentures when a one stage surgical approach is applied. It is intended for the restoration of a patient's chewing function.

INTRODUCTION

BBX1, BBX2, BBX1MO, BBX1MC dental implants are similar to the predicate ISI One-Piece Dental Implant from OCO Biomedical, K 033392 and predicate TSI Two-Piece Dental Implant from OCO Biomedical, K 090174. The BBX1, BBX2, BBX1MO and BBX1MC dental implant series features secondary threads which have various longitudinal and axial grooves starting from apical tip and finishing up to the full primary thread length. These axial grooves are called secondary threads or helix threads. The dental implant diameter limits the depth of these longitudinal and axial grooves.

DEVICE DESCRIPTION

BBX1, BBX1MO, BBX1MC and BBX2 dental implants are tapered implants whose material composition of the implants is titanium alloy Grade 5 ELI (Titanium 6 AL 4V), conforming to ASTM F-136 *(Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401).* Surface treatment features include air blasting with Biphasic Calcium Phosphate (CaPO4) and HA micro particles, followed by acid passivation and cleaning, conforming to ASTM F1088 *Surface Treatment HA,* ASTM F-86 *(Passivation),* and ASTM F1185-03 *Trace Elements.*

BBX1, BBX1MO, BBX1MC and BBX2 dental implants are all provided with screw thread and helix shape inclined grooves. For dental implant series BBX1, BBX1MO and BBX1MC, the shoulder or abutment is integrated, that is, not a separate part of the whole implant. They are one piece dental implants.

Dental implants series BBX2 consists of three parts, one straight abutment, one screw and the implant body.

BBX1, BBX2, BBX1MO and BBX1MC dental implants consist of a threaded area, a transgingival area, mini threads, an implant body area and a vertical abutment. Additional device description features are shown in the Comparison Chart below.

EQUIVALENCE TO MARKETED DEVICE

BBX1, BBX1MO and BBX1MC:

Primary Predicate - OCO Biomedical ISI one piece dental implants (K033392)

Reference devices – K100932 and K081653

BBX2:

Primary Predicate - OCO Biomedical TSI two piece straight abutment dental implants (K090174)

DEVICE COMPARISON CHART:

	Subject device	**Predicate device**	**Predicate device**	**Predicate device**
510(K) number	**K142846**	**K033392**	**K 100932**	**K 081653**
Device name	BBX1, BBX1MO, BBX1MC (one piece)	ISI- one piece	Inclusive ® Mini Implants	MII Implant
Manufacturer	Globaldental, Inc.	OCO-Biomedical, Inc.	Prismatic	IMTEC
Indication for use	BBX1, BBX2, BBX1MO, BBX1MC dental implants are intended for immediate loading in the bone of the maxillary or mandibular arch when optimal primary stability is achieved and appropriate occlusal loading. It is intended for use as support of crown bridges and overdentures when a one stage surgical approach is applied. It is intended for the restoration of a patient's chewing function.	The Immediate Stabilizing Implant (ISI) is a one-piece threaded dental implant with the abutment incorporated into the design for a single stage surgical procedure. The implant is intended to be surgically placed in the bone of the upper or lower jaw arches providing support for prosthetic devices resulting in the restoration of the patient's chewing function. Immediate loading can be obtained if implants are rigidly splinted.	Inclusive ® Mini Implants are set tapping threaded titanium screws indicated for long-term applications. Inclusive ® Mini Implants may also be used for provisional applications. These devices will allow immediate loading and long- term stabilization of dentures and provisional stabilization of dentures while standard implants heal. To be used for immediate loading only in the presence of primary stability and appropriate occlusal loading.	The MII Implant is intended to support single or multi-unit restorations in both long-term and temporary applications throughout the maxillary and mandibular arches. The MII Implants is indicated for immediate loading when good primary stability is achieved. Additionally, this device will permit stability and long-term fixation of upper and lower dentures.
Design	Non-Submerged Implant Design	Non-Submerged Implant Design	Non-Submerged Implant	Non-Submerged Implant
Implant Sterile	Yes	Yes	Yes	Yes
Sterilization Method	Gamma	Gamma	Gamma	Gamma
Surface Treatment	Ha/Calcium B-TCP-Bisphosphate,RBM	SLA	Blasted Etched Surface, SE to IMTEC K031106	Blasted and clean (SLA equivalent), machined
BBXMO, BBXMC Diameter and length combination	3 mm x 8mm 2.2, 2.5, 2.9, 3 mm x 10 mm	2.2, 2.5, 2.9, 3 mm x 12 mm 2.2, 2.5, 2.9, 3 mm x 14 mm	2.2, 2.5, 2,9, 3 mm x 16 mm	
BBX1 Diameter and length combinations	3, 4 and 5 mm x 8 mm 3, 4 and 5 mm x 10 mm	3, 4 and 5 mm x 12 mm 3, 4 and 5 mm x 14 mm	3, 4 and 5 mm x 16 mm	
Predicate Implant Diameters	**N/A**	3.25, 4, 5 mm	2.2, 2.5, 3.0 mm	2.9 mm
Predicate Implant Lengths	**N/A**	8, 10, 12, 14, 16 mm	10, 13, 15 mm	10, 13, 15, 18 mm
Abutment Diameters	3.0, 3.7 mm	3.0, 3.7 mm	1.65 mm	1.65 mm
Abutment Length	4.0 , 5.5 mm	OB-4.0, CB-5.5	4.0 mm	4.0 mm
Attachments	Straight Abutments- and components	Various abutments, and components	Various abutments, and components	Various abutments, and components.
Implant Materials	Ti-6Al-4V ELI, ASTM F-136	Ti-6Al-4V ELI ASTM F-136	Ti-6Al-4V ELI ASTM F-136	Ti-6Al-4V ELI ASTM F-136
Cover Screw Material	Ti-6Al-4V ELI, ASTM 136	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Product Code	DZE, NHA	DZE	DZE	DZE

	Subject Device	Predicate Device
510(K) number	K142846	K090174
Device name	BBX2 (two piece)	TSI Oco-Biomedical (two piece)
Manufacturer	Globaldental, Inc.	Oco-Biomedical, Inc.
Indication for use	BBX1, BBX2, BBX1MO, BBX1MC dental implants are intended for immediate loading in the bone of the maxillary or mandibular arch when optimal primary stability is achieved and appropriate occlusal loading. It is intended for use as support of crown bridges and overdentures when a one stage surgical approach is applied. It is intended for the restoration of a patient's chewing function	The TSI -and ERI Dental Implants are artificial root structures intended for permanent surgical implantation in the bone for the purpose of single or multiple tooth replacements (splinted or free standing), or for stabilization of a prosthetic system, such as artificial teeth in order to restore the patient's chewing function.
Design	Non-submerged implant design	Submerged implant design
Implant Sterile	Yes	Yes
Sterilization method	Gamma radiation	Gamma radiation
Surface treatment	Biphasic Calcium Phosphate Air blasted, passivation	SLA
BBX2 Implant Diameter and length Combinations	3.25, 4, 5 mm x 8 mm 3.25, 4, 5 mm x 12 mm 3.25, 4, 5 mm x 16 mm 3.25, 4, 5 mm x 10 mm 3.25, 4, 5 mm x 14 mm	
Implant diameter	3.25, 4, 5mm	3.25, 4, 5mm
Implant length	8, 10, 12, 14, 16	8, 10, 12, 14, 16
Abutment length	4.0, 5, 7mm	2, 3, 4, 5, 5.5, 7 mm
Abutment diameter (platform)	3.7, 4.7, 5.7mm	3, 4, 5 mm
Attachment	Straight abutments and Components	Angular and straight Abutments
Packaging	Tyvek, Ultem	Tyvek, Ultem
Implant material	Grade 5 titanium alloy (Ti6Al4V) ELI ASTM F-136	Grade 5 titanium alloy (Ti6Al4V) ELI ASTM F-136
Cover screw material	Gr.5 Ti6Al4V ELI	Grade 5 Ti6Al4V ELI
Product code	DZE, NHA	DZE

BBX1, BBX2, BBX1MO and BBX1MC have similarities to the predicate devices of ISI (K033392) and TSI (K090174) from OCO-Biomedical, Inc. Although the *Indications for Use* language differs between the subject and predicate devices, they all share the same intended use, which is a permanent dental implant placement in the bone of the maxillary or mandibular arch. Both are self-tapping implants. The subject devices and predicates have the same operating principles, are made from the same materials and have similar packaging and sterilization process.

A primary technological difference between the proposed and primary predicate devices is that the proposed device is available in certain diameter and length combinations not featured in the primary predicate device. To demonstrate the substantial equivalence of the proposed device, reference devices K100932 and K081653 were introduced, such that equivalent implant diameter and length combinations complemented those featured in the proposed device, thereby supporting the substantial equivalence of the proposed device to its predicates.

A second difference between the proposed and predicate devices is the fact that self-cutting grooves travel the entire length of the proposed device, whereas the predicate devices feature grooves only in the apical portion. However, the dental implant diameter dictates the depth of the longitudinal grooves, thereby avoiding a new worst-case scenario in the proposed implant. BX1, BX1MO and BBX1MC are substantially equivalent to the OCO-biomedical implant predicate K033392. They are manufactured using Titanium Grade 5 metal alloy ELI, one-piece component, meaning that the abutment and implant portions are combined and fully integrated (no connection).

BBX2, which is a two-component dental implant is substantially equivalent to the TSI Two-piece dental implant from Oco Biomedical implant K090174. The material is Ti Grade 5 ELI Ti6Al-4V.

PERFORMANCE DATA

Nonclinical Testing

The subject device features technological characteristics previously cleared in other devices. Biocompatibility testing was completed in accordance with the requirements of ISO 10993-5, *Biological Evaluation of Medical Devices—Part 1: Evaluation and Testing within a Risk Management Process for a permanent implant device with tissue/bone contact*. We have conducted every phase under the ASTM-F-136 standards and blasted them with HA/B-TCP BIPHASIC CALCIUM PHOSPHATE. Fatigue testing was not conducted since no angled abutments are included in the subject device system.

Non-clinical testing was performed in accordance to the following:

- ISO 10993-5 Biological Evaluation of Medical Devices – Cytotoxicity
- ISO 11137-2-2006 Sterilization
- ISO 17665-1 moist heat sterilization validation
- ASTM F1185-03 – trace elements
- ASTM F-136 material Ti6A-4V ELI
- ASTM F1088 Standard for Beta TCP
- ASTM F88, F1929, F2096 and F1140

CONCLUSION

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject device and predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and diameter, height and angle of the abutments. The subject and predicate devices are packaged in similar materials and sterilized using similar methods. Any differences in the technological characteristics do not raise new concerns.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.