DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 31, 2017

EBI Inc.
% April Lee
Consultant
Withus Group Inc.
2531 Pepperdale Drive
Rowland Heights, California 91748

Re: K170031
Trade/Device Name: Internal Octa Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: July 27, 2017
Received: August 3, 2017

Dear April Lee:

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,

Andrew I. Steen -S

for Lori A. Wiggins, MPT, CLT
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170031

Device Name
Internal Octa Implant System

Indications for Use *(Describe)*
The Internal Octa Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The Internal Octa Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

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

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Device Information

- Trade Name: Internal Octa Implant System
- Common Name: Dental Implant System
- Classification Name: implant, endosseous, root-form
- Product Code: DZE
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date prepared: 08/31/2017

General Description

An endosseous dental implant is a device made of Pure Titanium Grade 4. Internal Octa Implant System has been designed to accommodate the following dental implant restoration protocols; Immediate or Early loading, immediate placement or one or two stage placements. Internal Octa Implant Systems help patients who have partial or whole teeth loss mastication to chew as dental implant. The Internal Octa Implant System has an internal connection. The surface of the system has been treated with SLA (Sandblast, Large grit Acid etched).

There are 3different kinds of fixtures, BLT III, Precision III and LISA Implants. The only differences between these implants are designs and dimensions. The appearance of implants is different depending on the presence of cutting edge and taper. The Fixtures are supplied sterile.

The ranges of the fixtures' dimensions are below:

	BLT III Implant	Precision III Implant	LISA Implant
Implant Type	Bone Level	Tissue Level	Bone Level
Platform Diameter	4.1, 4.8mm	4.8, 6.5mm	4.1, 4.8mm
Body Diameter	4.1, 4.8mm	3.3, 4.1, 4.8mm	4.1, 4.8mm
Length	7.2, 7.7, 8.2, 8.7, 9.2, 9.7, 10.2, 10.7, 11.2, 11.7, 12.2, 12.7, 13.2, 13.7, 14.2 mm	8.3, 9.3, 10.3, 11.3, 12.3, 13.3, 14.3, 15.3 mm	11.2, 12.2 mm
Pitch	0.8mm	1.25mm	0.8mm
Unique features	It is made of Pure Titanium Grade 4. The surface treated with SLA (Sandblast, Large grit Acid etched).	It is made of Pure Titanium Grade 4. The surface treated with SLA (Sandblast, Large grit Acid etched).	It is made of Pure Titanium Grade 4. The surface treated with SLA (Sandblast, Large grit Acid etched). It has a concave appearance to be placed in the narrow ridge area.

Indication for Use

The Internal Octa Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The Internal Octa Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Materials:

The devices are fabricated from CP Titanium (Grade 4) that conforms to ASTM F67 for Dental Implant.

Performance Data (Bench Testing):

The subject device was tested to evaluate its substantial equivalence according to the following standards:

- Biocompatibility Testing such as cytotoxicity, sensitization, irritation and acute systemic toxicity was performed in accordance with ISO 10993-1:2009
- Surface roughness demonstration, surface SEM, and surface EDS
- LAL Endotoxin testing in accordance with ANSI/AAMI ST 72:2011, USP <85> and <161>

Below test was performed for primary predicate devices and leveraged for the subject device:

- Sterilization Test according to ISO 11137-1,-2,-3 referenced in K073116
- Shelf life Validation Test according to ISO 11607-1, -2, and ASTM F1980-07 referenced in K073116

The results of the above tests have met the criteria of the standards, and demonstrated the substantial equivalence with the predicate device.

Predicate Devices:

The subject device is substantially equivalent to the following predicate devices:

1) BLT III Implants

	Subject Device	Primary Predicate	Reference Predicate
Company	EBI Inc.	EBI Inc.	OSSTEM Implant Co.,Ltd.
Device Name	Internal Octa Implant System	EBI Internal Implant	ETIII SA Fixture
510(k) Number	NA	K073116	K101096
Device Classification Name	Implant, Endosseous, Root-form	Implant, Endosseous, Root-form	Implant, Endosseous, Root-form
Classification Product Code	DZE	DZE, NHA	DZE
Regulation Number	21 CFR872.3640	21 CFR872.3640	21 CFR872.3640
Intended Use	The Internal Octa Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The Internal Octa Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	EBI Implant System is intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.	ET III Fixture System is indicated for use in partially or fully edentulous mandibles and maxillae, in support or single or multiple-unit restorations including; cemented retained, screw retained, or overdenture restorations, and terminal or intermediate abutment support for fixed bridgework.
Material	Titanium Gr.4	Titanium Gr.4	Titanium Gr.4
Design			
Body Diameters	4.1, 4.8mm	3.3 – 4.8 mm	3.5 – 5.0 mm
Platform Diameters	4.1, 4.8mm	4.8, 6.5mm	3.5 – 5.0 mm
Total Lengths	7.2-14.2 mm	6-15.3 mm	7-15 mm
Connection Type	Internal Octa	Internal Octa	Internal Octa
Surface Treatment	SLA	RBM	SLA
Gamma Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf Life	5 years	5 years	5 years
Implant Type	Bone Level	Bone Level	Bone Level

2) Precision III Implant

	Subject Device	Primary Predicate
Company	EBI Inc.	EBI Inc.
Device Name	Internal Octa Implant System	EBI Internal Implant
510(k) Number	NA	K073116
Device Classification Name	Implant, Endosseous, Root-form	Implant, Endosseous, Root-form
Classification Product Code	DZE	DZE, NHA
Regulation Number	21 CFR872.3640	21 CFR872.3640
Intended Use	The Internal Octa Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The Internal Octa Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	EBI Implant System is intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.
Material	Titanium Gr.4	Titanium Gr.4
Design		
Body Diameters	Regular: 3.3, 4.1, 4.8 mm Wide: 4.8 mm	Regular: 3.3, 4.1, 4.8 mm Wide: 4.8 mm
Platform Diameters	4.8, 6.5 mm	4.8, 6.5 mm
Total Lengths	8.3-15.3 mm	6-15.3 mm
Connection Type	Internal Octa	Internal Octa
Surface Treatment	SLA	RBM
Gamma Sterilization	Radiation Sterile	Radiation Sterile
Shelf Life	5 years	5 years
Implant Type	Tissue Level	Tissue Level

3) LISA Implant

	Subject Device	Primary Predicate	Reference Predicate
Company	EBI Inc.	EBI Inc.	DIO Department, DSI, Inc
Device Name	Internal Octa Implant System	EBI Internal Implant	SM® IMPLANT SYSTEMS
510(k) Number	NA	K073116	K061797
Device Classification Name	Implant, Endosseous, Root-form	Implant, Endosseous, Root-form	Implant, Endosseous, Root-form
Classification Product Code	DZE	DZE, NHA	DZE, NHA
Regulation Number	21 CFR872.3640	21 CFR872.3640	21 CFR872.3640
Intended Use	The Internal Octa Implant System is intended for placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients. The Internal Octa Implant System is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	EBI Implant System is intended for immediate, delayed, or conventional placement in the maxillary and/or mandibular arches to support crowns, bridges, or overdentures in edentulous or partially edentulous patients.	The SM® Implant System is anendosseous dental implant is indicated for surgical placement in theupper and lower jaw arches, to provide a root form means for single or multiple units' prostheticappliance attachment to restorea patient's chewing function. Implants can be placed withconventional two stage surgical process with an option fortransmucosal healing or they can beplaced in a single stage surgical process for immediate loading. Immediate loading isrestricted tothe anterior mandible, based on four splinted interforminal placed implants, and notindicated forsingle, unsplinted implants. Patients must besubject for dental treatment withendosseousimplants.
Material	Titanium Gr.4	Titanium Gr.4	Titanium Gr.4
Design			
Body Diameters	4.1, 4.8mm	Regular: 3.3, 4.1, 4.8 mm Wide: 4.8 mm	3.8, 4.5, 5.3 mm
Platform Diameters	4.1, 4.8mm	4.8, 6.5 mm	3.8, 4.5, 5.3 mm
Total Lengths	11.2, 12.2 mm	6-15.3 mm	8-14 mm

Connection Type	Internal Octa	Internal Octa	Internal Octa
Surface Treatment	SLA	RBM	RBM
Gamma Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
Shelf Life	5 years	5 years	5 years
Implant Type	Bone Level	Tissue Level	Bone Level

Substantial Equivalence Discussion

The Internal Octa Implant System has a substantially equivalent intended use as the identified predicates. The subject device is similar in fundamental scientific technology to the predicate device in that they all have been designed, manufactured and tested in compliance with FDA's Class II special controls guidance document root-form endosseous dental implants and endosseous dental implant abutment, and they are all constructed of titanium.

The subject and primary predicate devices are similar in indications, design, technology, functions, dimensions, and material.

The differences between the subject device and the primary predicate are:

1) Surface Treatment Method
   The surface treatment method of the subject device is SLA (Sandblast, Large grit Acid etched) and the surface treatment method of the primary predicate device is RBM (Resorbable Blasted Media). To support this discrepancy, the predicate, K101096 is selected as reference and biocompatibility testing, surface roughness demonstration, surface SEM, and surface EDS were performed on the subject device.

2) Slight differences in fixture designs, especially LISA Implant
   LISA Implant has a concave appearance to be placed in the narrow ridge area, which is difference of the shape between the subject and primary predicate, K073116. To support this discrepancy, the predicate, K061797 is selected as reference.

Any differences in technology characteristics are accompanied by information that demonstrated the device is substantially equivalent as the predicates and do not raise different questions of safety and effectiveness than the predicate.

Conclusion

The Internal Octa Implant System, subject device of this submission, constitutes a substantially equivalent medical device, meeting all the declared requirements of its intended use. The risks of using the device as recommended pose no greater risks than any other implant systems. This system has the same intended use and fundamental scientific technology as its predicate devices. Therefore, Internal Octa Implant System and its predicates are substantially equivalent.