



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 27, 2015

Ebi Inc
c/o Ms. April Lee
Consultant
WithUS Consulting
2531 Pepperdale Drive
Rowland Heights, CA 91748

Re: K142426
Trade/Device Name: Ebi External Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: February 23, 2015
Received: February 27, 2015

Dear Ms. 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 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

Indication for Use

510(K) Number (if known): K142426

Device Name: EBI Dental Implant System

Indication for Use:

EBI Dental 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.

Prescription Use X

AND/OR

Over-The-Counter _____

(Part 21 CFR 801 Subpart D)

(Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



EBI Inc.

124, Uisong-gil, Amnyang-myeon, Gyeongsan-si, Gyeongsangbuk-do, South Korea, 712-825
Tel. 82- 53-817-7767 / Fax. 82-53-817-7768

510(k) Summary

Submitter

EBI Inc.
Mi Sook Kim
124, Uisong-gil, Amnyang-myeon, Gyeongsan-si
Gyeongsangbuk-do 712-825
South Korea
Email: dej@ebiimplant.com
Tel. +82-53-817-7767
Fax. +82-53-817-7768

Official Correspondent

WithUS Consulting
April Lee
2531 Pepperdale Drive,
Rowland Heights, CA 91748
USA
Email: withus6664@gmail.com
Phone: 1-909-274-9971
Fax: 1-909-460-8122

Device Information

- Trade Name: EBI External Implant System
- Common Name: Dental Implant System
- Classification Name: implant, endosseous, root-form
- Product Code: DZE, NHA
- Panel: Dental
- Regulation Number: 872.3640
- Device Class: Class II
- Date prepared: 3/23/2015

General Description

An endosseous dental implant is a device made of a material such as Pure Titanium Grade 4 and Titanium alloy (Ti-6Al-4V ELI). EBI Implant system has been designed to accommodate the following dental implant restoration protocols; Immediate or Early loading, immediate placement or one or two stage placement. EBI Implant systems help patients who have partial or whole teeth loss mastication to chew as dental implant. The EBI External Implant System has an external connection.

The surface of the system has been treated with RBM (Resorbable Blasted media).

The Fixture diameters are 3.25, 3.3, 3.75, 4, 4.1, 4.8, 5, 5.5, 6, 6.5, 7mm and lengths are 7, 8, 8.1, 8.5, 9, 9.6, 10, 11, 11.5, 12, 12.6, 13, 14, 14.6, 15mm in this system.

The contained various abutments and accessories in the system are cover screw, healing abutment, cemented abutment, temporary abutment, healing cap, impression coping, analog, fixture mount, Ti-screw, angled abutment, impression guide pin, gold UCLA abutment and locator.

Fixtures and abutments are packaged separately. The Fixtures are supplied sterile and the abutments and accessories are provided non-sterile. The abutments and accessories should be sterilized before use.



EBI Inc.

124, Uisong-gil, Amnyang-myeon, Gyeongsan-si, Gyeongsangbuk-do, South Korea, 712-825
Tel. 82- 53-817-7767 / Fax. 82-53-817-7768

Indication for Use

EBI Dental 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.

Materials:

The devices are fabricated from CP Titanium (Grade 4) that conforms to ASTM F67 for Dental Implant and Titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F136 for Abutments.

Performance Data (Bench Testing):

Fatigue Testing was performed in accordance with ISO 14801:2007 under the worst case scenario.

Predicate Devices:

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

- K073116, EBI Internal Implant System manufactured by EBI, Inc.
- K111216, OSSEOTITE2 Dental Implants manufactured by BIOMET 3I, Inc.
- K063286, OSSEOTITE; OSSEOTITE NT; XP; TG; OSSEOTITE manufactured by Implant innovations inc.
- K052369, Exfeel Implant System manufactured by Megagen Implant Co., Ltd.

Comparison to Predicate Devices:

	Subject Device	Predicate Device	Predicate Device	Predicate Device	Predicate Device
Company	EBI Inc.	EBI, Inc	BIOMET 3I, INC.	IMPLANT INNOVATIONS, INC.	MEGAGEN IMPLANT CO., LTD.
Device Name	EBI External Implant System	EBI Internal Implant System	OSSEOTITE 2 DENTAL IMPLANTS	OSSEOTITE; OSSEOTITE NT; XP; TG OSSEOTITE	EXFEEL IMPLANT SYSTEM

510(k) Number	N/A	K073116	K111216	K063286	K052369
Device Classification Name	Same as predicate	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form	Implant, Endosseous, Root-Form
Classification Product Code	DZE, NHA	DZE, NHA	DZE	DZE	DZE
Regulation Number	872.3640	872.3640	872.3640	872.3640	872.3640
Intended Use	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	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	Intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth utilizing delayed or immediate loading or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures	Intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment in single tooth utilizing delayed or immediate loading or with a terminal or intermediary abutment for fixed or removable bridgework, and to retain overdentures	Intended to be placed in the upper or lower jaw to support prosthetic devices, such as artificial teeth, and to restore a patient's chewing function
Material	Commercially Pure Titanium & Titanium Alloy	Commercially Pure Titanium & Titanium Alloy	Commercially Pure Titanium & Titanium Alloy	Commercially Pure Titanium	Commercially Pure Titanium
Design					



EBI Inc.

124, Uisong-gil, Amnyang-myeon, Gyeongsan-si, Gyeongsangbuk-do, South Korea, 712-825
Tel. 82- 53-817-7767 / Fax. 82-53-817-7768

Implant Diameters	3.25,3.3,3.75 4,4.1,4.8,5,5.5 6,6.5,7mm	3.3-4 mm	3.25,3.75,4,5,6mm	3.25,3.75,4,5,6mm	3.3,3.75,4,4.5, 5,5.5mm
Implant Lengths	7,8,8.1,8.5,9,9.6, 10,11,11.5,12,12.6, 13,14,14.6,15mm	6-15 mm	6.5,8.5,10 11.5,13,15mm	7,8.5,10, 11.5,13,15mm	7,8.5,10, 11.5,13,15mm
Components	Implants and various abutments	Implants and various abutments	Implants and various abutments	Implants and various abutments	Implants and various abutments
Connection Type	External	Internal	External	External	External
Surface Treatment	Resorbable Blast Media (RBM)	Resorbable Blast Media (RBM)	Full OSSEOTITE	Full OSSEOTITE	Resorbable Blast Media (RBM)
Gamma Sterilization	Yes	Yes	Yes	Yes	Yes
Shelf Life	5 years	5 years	5 years	5 years	5 years
Angulation of Angled Abutment	15°, 25°	15°, 25°	15°	15°	15°, 25°

Substantial Equivalence Discussion

The EBI External 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 predicate devices are similar in indications, design, technology, functions, dimensions and materials.

The only differences between the subject device and the predicate devices are slight differences in fixture designs and diameters.

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

Conclusion

The EBI External 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, EBI External Implant System and its predicates are substantially equivalent.