DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 10, 2018

Jeil Medical Corporation
Ms. Hyeroung Lee
RA Manager
702-706, 804, 805,807, 812-HO, 55,
Digital-ro34-gil, Guro-gu, Seoul, 152-728
Korea

Re: K143730
Trade/Device Name: GBR System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY, DZL
Dated: May 8, 2015
Received: May 11, 2015

Dear Ms. Lee:

This letter corrects our substantially equivalent letter of June 10, 2015

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, 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)*
K143730

Device Name

GBR System

Indications for Use *(Describe)*
Indications for Use (Describe)

The GBR System is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity.

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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K143730

510(k) Summary

[As required by 21 CRF 807.92]

1. Date Prepared: 4 June 2015

2. Submitter's Information

- Name of Sponsor: Jeil Medical Corporation
  - Address: 702•703•704•705•706•804•805•807•812-ho, 55, Digital-ro34-gil, Guro-Gu, Seoul, 152-728, Korea
- Contact Name: Hyeroung LEE (Ms.) / RA Manager
  - Telephone: +82 2 850 3500
  - Fax: +82 2 850 3535
  - Email Address: carine@jeilmed.co.kr
- Registration Number: 3004049923
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification

- Trade Name: GBR System
- Common Name: Bone Screw, Bone Plate

Product Code	Device Name	Device Classification	Regulation Number	Regulation Description
JEY	Plate, Bone	2	872.4760	Bone Plate
DZL	Screw, Fixation Intraosseous	2	872.4880	Intraosseous Fixation Screw or Wire

4. Identification of Predicate Device(s)

The identified predicate device within this submission is shown as follows:

- 510(k) Number: K050669
- Applicant: Jeil Medical Corporation
- Common Name: Bone Screw, Bone Plate
- Device Name: Jeil Bone Fixation System

There are no significant differences between the Model GBR System and the predicate

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device that would adversely affect the use of the proposed device. It is equivalent to the predicate in design, function, materials, and operational principles as internal fixation components.

5. Description of the Device

The GBR System is rigid fixation consisting of plates and screws in various configurations, shapes and sizes as follows:

	Screw			Plate	
	Auto Screw	**GBR Auto Screw**	**Tenting Screw**	**Mesh Plate**	**GBR Mesh**
Type/ Configuration	14-AT-003, 14-AT-004, 14-AT-005, 14-AT-006, 14-AT-008, 14-AT-010, 14-AT-012, 16-AT-003, 16-AT-004, 16-AT-005, 16-AT-006, 16-AT-008, 16-AT-010, 16-AT-012	14-AT-003G, 14-AT-004G, 14-AT-005G, 14-AT-006G, 14-AT-008G, 14-AT-010G, 14-AT-012G, 14-AT-003G-25, 14-AT-004G-25, 14-AT-005G-25, 14-AT-006G-25, 14-AT-008G-25, 14-AT-010G-25, 14-AT-012G-25	16-TT-010	12-ME-001-01, 12-ME-001-02, 12-ME-002-01, 12-ME-002-02, 12-ME-003-01, 12-ME-003-02, 12-GM-001-01, 12-GM-001-02, 12-GM-002-01, 12-GM-002-02	12-GM-P01, 12-GM-P02, 12-GM-J01, 12-GM-L01
Material	ASTM F136, Titanium Alloy (Ti-6Al-4V)			ASTM F67, Unalloyed Titanium	

The GBR System is made of Unalloyed Titanium and Titanium Alloy (Ti-6AL-4V), which meet ASTM F67, Standard Specification for Unalloyed Titanium for Surgical Implant Applications, and ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known biocompatibility.

The device screw is available in three different types, Auto Screw, Tenting Screw and GBR Screw. The Auto Screw is for stabilizing the mesh plate. The GBR Auto Screw has wide head design which is well suited for GBR mesh. The Tenting Screw is comprised with a body and a cap. It is effective in maintaining the space between the mesh and the bone.

- The GBR Auto Screw is provided with head diameter 2.5 mm or 3.0 mm, thread diameter 1.4 mm, and length from 3.0 mm to 12.0 mm.
- The Auto Screw is provided with head diameter 2.0 mm or 2.5 mm, thread diameter 1.4 mm or 1.6 mm, and length from 3.0 mm to 12.0 mm
- The Tenting Screw is proved with head diameter 2.7 mm, thread diameter 1.4 mm and length 10.0 mm.

The device plate is provided in two different types, mesh plate and GBR mesh plate.

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- The Mesh Plate is very thin, soft and elastic but has strong membrane with good suture retention. The extremely high flexibility of this mesh plate allows free fitting, even to irregular surfaces.
- The GBR Mesh Plate is suited for horizontal and vertical bone volume augmentation of implants sites using guided bone. The GBR Mesh Plate is suitable for multi-case situations; the product allows bone formation and spatial retention for stable implant. The GBR Mesh Plate has flexibility with thin thickness, and the pre-cut design makes the desired shape form easier.

The device system also includes various manual surgical instruments, such as mesh puncher, screwdriver handle, screw block, driver shaft and drill bit.

The GBR System not provided sterile. It is required to be sterilized via autoclave method to reach a SAL of 10^{-6} by the hospital prior to surgery. The sterilization method is presented in the instruction, which was validated per ISO 17665-1: 2006 Sterilization of health care products – Moist heat - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices.

The GBR System is provided as silver color which is casted according to the anodizing technique while apply 5 V ~ 10 V electric energy to the titanium.

Screw		
Type	**Catalog Number**	**510(k) Number**
Auto Screw	14-AT-003, 14-AT-004, 14-AT-006, 14-AT-008, 14-AT-010, 14-AT-012, 16-AT-004, 16-AT-006, 16-AT-008, 16-AT-010,	**K050669**
	14-AT-005, 16-AT-003, 16-AT-005, 16-AT-012	**K143730**

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GBR Auto Screw	14-AT-003G, 14-AT-004G, 14-AT-005G, 14-AT-006G, 14-AT-008G, 14-AT-010G, 14-AT-012G, 14-AT-003G-25, 14-AT-004G-25, 14-AT-005G-25, 14-AT-006G-25, 14-AT-008G-25, 14-AT-010G-25, 14-AT-012G-25	**K143730**
Tenting Screw	16-TT-010	**K143730**
Plate		
Type	**Catalog Number**	**510(k) Number**
Mesh Plate	12-ME-001-01, 12-ME-001-02,	**K050669**
	12-ME-002-01, 12-ME-002-02, 12-ME-003-01, 12-ME-003-02, 12-GM-001-01, 12-GM-001-02, 12-GM-002-01, 12-GM-002-02	**K143730**
GBR Mesh Plate	12-GM-P01, 12-GM-P02, 12-GM-J01, 12-GM-L01	**K143730**

The GBR System is consisted of a previously cleared screw and plate (K050669) as well as new screws and plates with different lengths and sizes.

The new types of Auto Screw include different lengths for user's convenience. For 14-AT-series, we added a new product with a length of 5mm. For 16-AT-series, we added products with lengths of 3mm, 5mm, and 12mm. Also, for the new type of GBR Auto Screw, the diameter of the screw head was extended so that it would improve the stability when fixing the mesh plate. The new type of Tenting Screw is for implanting the screw body during Guided Bone Regeneration procedure and it is also for fixing the Plate through the Cap Screw in order to maintain enough space for bone graft materials.

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The new types of mesh plates include various products with different sizes, thickness, and pore sizes for the user's convenience. 12-GM-P01 and 12-GM-P02 of the new types of GBR Mesh Plates are designed to be used together when Guided Bone Regeneration procedure is needed during dental implant surgery. 12- GM-J01 and 12-GM-L01 are the new types with slots for easy modification to suit the surgical site.

6. Intended Use

The GBR System is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity.

7. Technological Characteristics

The GBR System is a rigid fixation consisting of plates and screws in various configurations, shapes and sizes as follows:

• **Screw**

Unit (mm)

Type		**Head Diameter**	**Thread Diameter**	**Length**
Auto Screw		Ø 2.0, 2.5	Ø 1.4, 1.6	3, 4, 5, 6, 8, 10, 12
GBR Auto Screw		Ø 2.5, 3.0	Ø 1.4	3, 4, 5, 6, 8, 10, 12
Tenting Screw	**Body**	Ø 2.7	Ø 1.6	10
	Cap	Ø 2.5	Ø 1.4	1.6

• **Plate**

Unit (mm)

Type		**Size**	**Thickness**	**Pore Diameter**
Mesh Plate	**ME**	37.0 * 24.0 49.0 * 37.0 99.0 * 74.0	0.1 0.2	Ø 1.48 ~ 1.88
	GM	37.0 * 25.1 75.0 * 51.0	0.1 0.2	Ø 0.8
GBR Mesh Plate		16.6 * 10.0 28.0 * 10.0 53.0 * 29.0 41.0 * 21.9	0.15	Ø 0.8

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Non-Clinical Test Summary:

A non-clinical evaluation, based on ASTM F543-13, has been done. The evaluation of the applicable market data showed that the bone screw does not pose known or new clinical concerns from the similar medical devices that are currently on the market. Based on those results clinical test have not been executed.

The following tests were performed with the predicate devices:

- Screws - Driving torque test per ASTM F543-13
  - Axial pull-out test per ASTM F543-13
  - Torsion test per ASTM F543-13
- Plate - Tensile Strength

The results of this testing indicate that the GBR System is equivalent to the predicate device.

Clinical Test Summary:
No clinical studies were considered necessary and performed.

8. Substantial Equivalence

Parameter	Proposed	Predicate	Remark
	GBR System	Jeil Bone Fixation System	
510(k) Number	K143730	K050669	-
Manufacturer	Jeil Medical Corporation	Jeil Medical Corporation	-
Indications for Use	The GBR System is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity.	The Jeil Bone Fixation System is intended for use in stabilizing and fixating bone grafts, bone filling material and/or barrier membranes used for guided bone/tissue regeneration in the oral cavity.	Same

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Parameter	Proposed	Predicate	Remark
	GBR System	Jeil Bone Fixation	
Catalog Number	**Bone Plate** 12-ME-001-01, 12-ME-001-02, 12-ME-002-01, 12-ME-002-02, 12-ME-003-01, 12-ME-003-02, 12-GM-001-01, 12-GM-001-02, 12-GM-002-01, 12-GM-002-02, 12-GM-P01, 12-GM-P02, 12-GM-J01, 12-GM-L01	**Bone Plate** 12-ME-001-01, 12-ME-001-02	Performance Testing
	Bone Screw 14-AT-003, 14-AT-004, 14-AT-005, 14-AT-006, 14-AT-008, 14-AT-010, 14-AT-012, 16-AT-003, 16-AT-004, 16-AT-005, 16-AT-006, 16-AT-008, 16-AT-010, 16-AT-012,	**Bone Screw** 14-AT-003, 14-AT-004, 14-AT-006, 14-AT-008, 14-AT-010, 14-AT-012, 16-AT-004, 16-AT-006, 16-AT-008, 16-AT-010	Performance Testing

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Parameter		Proposed	Predicate	Remark
		GBR System	Jeil Bone Fixation	
		14-AT-003G, 14-AT-004G, 14-AT-005G, 14-AT-006G, 14-AT-008G, 14-AT-010G, 14-AT-012G, 14-AT-003G-25, 14-AT-004G-25, 14-AT-005G-25, 14-AT-006G-25, 14-AT-008G-25, 14-AT-010G-25, 14-AT-012G-25, 16-TT-010		
Plate Shape		Mesh Type	Mesh Type	Performance Testing
Plate Thickness		12-ME/GM-Series-01 : 0.1 mm 12-ME/GM-Series-02 : 0.2 mm 12-GM-Series : 0.15 mm	12-ME-Series-01 : 0.1 mm 12-ME-Series-02 : 0.2 mm	Performance Testing
Screw Type		Self-Drilling, Tenting	Self-Drilling	Performance Testing
Screw Diameter		14-Series: 1.4 mm, 16-Series: 1.6 mm	14-Series: 1.4 mm, 16-Series: 1.6 mm	Same
Bone plates are used with general surgical instrumentation		Yes	Yes	Same
Material	Plate	Titanium (ASTM F67)	Titanium (ASTM F67)	Same
	Screw	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Same
Surface casting		Plate – Anodizing	Plate – Anodizing	Same

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Parameter	Proposed	Predicate	Remark
	GBR System	Jeil Bone Fixation	
Sterilization	Non-sterile, Steam sterilization prior to use	Non-sterile, Steam sterilization prior to use	Same
Single Use	Yes	Yes	Same

Some of the plates and screws of the subject devices are the same with several models of predicate device (K050669), but the subject device added more types of plates and screws. When compared to the predicate devices, the GBR System presented in this submission is equivalent, in terms of the following:

- Intended Use
- Technological characteristics
- Operating principle
- Design features
- Performance
- Biocompatibility
- Materials
- Method of sterilization and sterility assurance level

9. Conclusion [21 CFR 807.92(b)(3)]

The GBR System is equivalent to currently marketed devices. Both the subject and the predicate devices share the same intended use. The subject device is made of the same materials and has similar dimensions and characteristics as does the predicate device. These devices are manufactured from titanium alloys used generally in this type of bone screw and bone plate device, manufactured and sold around the world. The subject device, the GBR System, is equivalent in design and uses the same principle of operation of the predicate device.

To summarize, the subject device is equivalent in design, material, intended use and function to the predicate device. It is concluded that the information included in this summary supports the substantial equivalence of the subject device.