DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 20, 2016

Osteonic Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt, Ste 417
Irvine, California 92620

Re: K160363
Trade/Device Name: Optimus CMF System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: Class II
Product Code: JEY, DZL
Dated: September 15, 2016
Received: September 20, 2016

Dear Priscilla Chung:

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,

Michael J. Ryan -S

for 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)*
K160363

Device Name
Optimus CMF System

Indications for Use *(Describe)*
Optimus CMF System is implantable bone plates and bone screws for maxillofacial and mandible surgery procedures including:

1. Fractures
2. Osteotomies
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K160363

510(k) Summary

Date: Oct 20, 2016

1. Applicant / Submitter:

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2. Submission Correspondent

Priscilla Chung
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3. Device:

- Proprietary Name – OPTIMUS CMF SYSTEM
- Common Name – Dental Bone Plate & Screw System
- Classification Name – Bone Plate

4. Predicate Device:

- Primary Predicate Device: K140037-OPTIMUS CMF SYSTEM by Osteonic Co., Ltd.
- Reference Predicate Device: K112457-LeForte System Bone Plate & Screw by Jeil Medical Corporation

5. Product Code & Regulation Number:

- Primary - JEY (21CFR 872.4760)
- Secondary - DZL

6. Device Description:

The system is comprised of plate and screw. The range of subject device plate's sizes is from 0.6 to 1.5mm thick. It is made of unalloyed Titanium (ASTM F67) and anodized in 4 colors (silver, blue, green and gold). The range of screw's diameters is from 1.3 to 2.0mm in lengths of 6.0 to 12mm. The screws are made of Ti-6Al-4V ELI titanium alloy (ASTM F136) and anodized in 3 colors (light blue, silver and gold).

The device is packed separately in a PE bag.The plate and screw aresingle use only, non-sterile products. The devices must be sterilized before use.

The screws are anodized in different colors to prevent confusion. The colors are selected for each model by diameter and so on. The devices are used as a pair (O-plate & O-screw, F-plate & F-screw) but sold individually (Not a kit or a set).

The IMF screw is for maxillomandibular fixation. The head has a relief groove in which wire or elastic bands can be wrapped around the screws which are temporarily implanted in the maxilla and mandible. It is intended for use as a bone screw in temporary fixation of the maxilla and mandible, providing indirect stabilization of fractures of the maxilla and/or the mandible. It is used independently, not with the plates.

7. Indication for use:

Optimus CMF System is implantable bone plates and bone screws for maxillofacial and mandible surgery procedures including:

1. Fractures
2. Osteotomies
3. Reconstructive procedures
4. Revision procedures where other treatments or devices have failed.

8. Non-clinical tests:

There are a number of differences between the unmodified devices and the modified devices as presented in this submission, however, the differences were evaluated through design control, risk analysis and verification & validation activities, and test results demonstrated that the differences do not raise a question of safety and effectiveness.

The following tests were performed on the subject device and the predicate devices.

- 4 Point Bending Test in accordance with ASTM F382-14 to evaluate strength (yield strength, bending structural stiffness, and bending strength)
- Torsional strength test and pullout force test in accordance with ASTM F 543 13 to evaluate strength

The test results of the subject device were overall higher than the predicatedevices supporting that the subject device is substantially equivalent to the predicate devices.

Validation of sterilization parameters and biocompatibility of the submission device are supported by sterilization validation and biocompatibility testing as provided in the primary predicate K140037.

9. Substantial Equivalence:

The subject device has the same device characteristics as the predicate (unmodified) device. They have the same intended use, raw material, and use concept and employ the same manufacturing processes including anodization and sterilization method. The differences are in shape and dimensions; however; the performance test data provided in this submission proves that this differences do not raise new issues in safety and performance.

	Subject Device	Primary Predicate Device	Reference Device
510K Number	K160363	K140037	K112457
Product Code	JEY, DZL		JEY, DZL
Manufacturer	OSTEONIC Co., Ltd.		Jeil Medical Corporation
Indications for Use	Optimus CMF System is implantable bone plates and bone screws for maxillofacial and mandible surgery procedures including: 1. Factures 2. Osteotomies 3. Reconstructive procedures 4. Revision procedures where other treatments or devices have failed.		This device is intended for use in selective trauma of the mid-face, reconstruction procedures and selective orthognathic surgery of the maxilla and chin.
Materials	Unalloyed Titanium and Titanium alloy		Unalloyed Titanium and Titanium alloy
Shape	▪ Plate Leforte I, Segmentalleforte I, Buttress, T and Straight types with various lengths.	▪ Plate Straight, Y, D-Y, X, L, Z, Square, Matrix, Orbital, Chin and Reconstruction types with various lengths.	▪ Plate L, T, Mesh, Straight, Y, H, Curved, Square, Quad, X, Calvarium, Hexagon, Double Y, RC, Z, I, Compression, Chin, Rigid straight, BSSO, Angled Reconstruction, MG, Orbital Mesh, A, Angled Locking, Prebending L, Curved Locking, Straight reconstruction Locking, Straight BSSO Locking, Angled Reconstruction Locking, Multi Reconstruction Locking, Straight Locking
	▪ Screw Pre-drilling screw, Self-drilling screw, IMF screw	▪ Screw Pre-drilling screw, Self-drilling screw, IMF screw	▪ Screw Common screw-Micro, Common screw-Mid, Common screw-Mini,

			Common screw-Maxi, Auto screw-Micro, Auto screw-Mid, Auto screw-Mini, Mini Locking Auto screw, Maxi Locking Auto screw, Mini Locking Common screw, Maxi Locking common screw
Dimensions	▪ Plate The plate thickness sizes range from 0.6 to 1.5mm. Length:21.5~36.5 Width: 4.5~30.00	▪ Plate The plate thickness sizes range from 0.4 to 2.6mm. Length: 11.6~39.9mm Width: 3.1 ~243.3mm	▪ Plate Plate length 5.2~223.5mm Thickness 0.2~2.5mm
	▪ Screw The diameters of the screws range from 1.3 to 2.0mm while lengths range from 6.0 to 12.0mm. (1) Pre-drilling screw Diameter: Ø1.3mm Length: 10.0, 12.0mm (2) Self-drilling screw Diameter: Ø1.3mm Length: 8.0, 10.0mm (3) IMF screw Diameter: Ø2.0mm Length: 6.0, 8.0, 10.0, 12.0mm	▪ Screw The diameters of the screws range from 1.3 to 2.7mm while lengths range from 3.0 to 20.0mm. (1)Pre-drilling screw Diameter: Ø1.3~ Ø2.7mm Length: 3.0~20.0mm (2) Self-drilling screw Diameter: Ø1.3~ Ø1.95mm Length: 3.0~14.0mm (3) IMF screw Diameter: Ø 1.6~ Ø2.0mm Length: 6.0~12.0mm	▪ Screw Screw outer(head) diameter 1.2~2.65mm, Inner diameter 0.7~1.6mm, Length 4.0~18.0mm
Surface Treatment	Anodizing		Plate: Anodizing Screw: N/A
Anodizing Color	▪ Plate Silver, blue, green and gold ▪ Screw Light blue, silver and gold	▪ Plate Silver, blue, green and gold ▪ Screw Light blue, silver, purple, blue, gold and green	▪ Plate Light blue, silver and gold ▪ Screw N/A

Sterilization	Non-sterile products	Non sterile
Usage	Single use only	Single use
Packaging	1EA/bag	1EA/bag

10. Conclusions:

Based on documentation supplied with this submission, conclusions drawn from design control, risk analysis and verification & validation activities demonstrate that the subject devices are substantially equivalent to the predicate device.