DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 1, 2015

OsteoMed L.P.
Ms. Anita Zacherl
Senior Regulatory Specialist
3885 Arapaho Road
Addison, TX 75001

Re: K143338
Trade/Device Name: OsteoMed ICON Modular Locking Fixation System
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: February 27, 2015
Received: March 2, 2015

Dear Ms. Zacherl:

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" (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 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,

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

Indications for Use

510(k) Number (if known): K143338

Device Name: OsteoMed ICON Modular Locking Fixation System

Indications for Use:

The ***OSTEOMED*** *ICON Modular Locking Fixation System* is indicated for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

The ***OSTEOMED*** *ICON Angulated Locking Plate System* implants and drills are intended for **single use only**.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Special 510(k) Summary

Name of Submitter: OsteoMed

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Contact Person: Anita Zacherl

Date Prepared: March 30, 2015

Device Proprietary Name: OsteoMed ICON Modular Locking Fixation System

Device Common Name: ICON Locking Fixation System

Classification Name: 21 CFR 872.4760, Plate, Bone

Product Code: JEY

Predicate Devices: **OsteoMed Modular Locking Fixation System, K080694**

Classification Name: Plate, bone (**21CFR 872.4760, Product Code JEY**)
Device Class: **II**

Summary:

Device Description:

The ***OSTEOMED*** *ICON Modular Locking Fixation System* is comprised of plates, screws and instrumentation utilized in the fixation of maxillofacial and mandibular fractures. The screw and plate interface allows up to 20 degrees of angulation within screw placement. The plating system allows for the use of locking standard screws, locking Auto-Drive™ screws, standard non-locking screws, safety screws and Auto-Drive™ screws, as needed.

The system features three modular blocks.

- The *1.6mm Midface System* consists of 1.6mm locking standard screws with lengths ranging from 3mm to 14mm, 1.6mm locking Auto-Drive™ screws with lengths ranging from 4mm to 8mm and 1.9mm safety screws with lengths ranging from 3mm to 14mm. The 1.6mm midface plates range in thicknesses of 0.6mm to 0.8mm.

- The 2.0mm *Midface/Mandible System* consists of 2.0mm locking standard screws with lengths 4mm to 18mm, 2.0mm locking Auto-Drive™ screws with lengths of 4mm to 8mm, and 2.3mm safety screws with lengths ranging from 4mm to 24mm. The midface plates range in thicknesses of 0.6mm to 0.8mm and the mandible plates range in thicknesses of 1.0mm to 1.5mm.

- The 2.8mm *Mandible System* consists of 2.0mm locking standard screws with lengths 6mm to 22mm, 2.4mm locking Auto-Drive™ screws with lengths of 6mm to 8mm, and 2.7mm safety screws with lengths ranging from 6mm to 22mm. The fracture plates range in thicknesses of 1.0mm to 1.5mm and the reconstruction plates range in thicknesses of 2.0mm to 2.8mm.

The instruments include drill bits, plate bending pliers, plate holding forceps, plate cutters, drill guides, cannulae, taps, countersinks, and screwdrivers to facilitate the placement of screws and modification of plates.

Indications for Use:

The ***OSTEOMED*** *ICON Modular Locking Fixation System* is indicated for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction.

The ***OSTEOMED*** *ICON Modular Locking Fixation System* implants and drills are intended for **single use only**.

Technological Characteristics:

The OsteoMed ICON Modular Locking Fixation System is recommended for fixation of maxillofacial and mandibular fractures.

The ICON Modular Locking Fixation System screws are made from Titanium Alloy (ASTM F-136). The plates are made from Titanium Alloy (ASTM F-136) or commercially pure Titanium (ASTM F-67). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade plastic**, the same materials used in the manufacture of the predicate devices. These materials are biocompatible.**

Performance/Clinical Data:

The OsteoMed ICON Modular Locking Fixation System 2.8mm plates were compared to the **OsteoMed 2.5mm Modular Locking Fixation System plates, K080694.** The ICON Modular Locking Fixation

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System plates underwent verification evaluation to ensure that the design features met the required mechanical strength criteria for their intended use. The intended use of the OsteoMed ICON Modular Locking Fixation System plates is the same as the **OsteoMed Modular Locking Fixation System plates**.

Performance equivalence was shown through the verification comparison to the predicate devices.

Clinical Testing is not required to support substantial equivalence.

Substantial Equivalence:

A design, dimensional, and performance comparison was performed to establish substantial equivalence to the legally marketed predicate devices listed in this summary. The basis of substantial equivalence for this device is based on similarities in intended use, material, function, performance, design, technology and operational principles to the OsteoMed Modular Locking Fixation System (K080694).

Comparison Table Modular Locking Fixation Mandible Module		
System / Device Name	***OSTEOMED ICON Modular Locking Fixation Mandible Module Reconstruction Plates***	***OSTEOMED Modular Locking Fixation System Mandible Module Reconstruction Plates***
510K Number	Pending	**K080694**
Classification	Class II 21 CFR 872.4760 JEY	Class II 21 CFR 872.4760 JEY
Indication for Use	The OsteoMed ICON Modular Locking Fixation System is indicated for fracture fixation in maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction. The implants and drills are intended for single use only.	The OsteoMed Modular Locking Fixation System is indicated for fracture fixation in cranio-maxillofacial trauma reconstruction, mandibular reconstruction and orthognathic reconstruction. The implants and drills are intended for single use only.
Plates	Various shapes	Various shapes
Recon Plate Thickness	2.8mm	2.5mm
Material (Recon Plates)	ASTM F-67	ASTM F-67
The 2.4mm Mandible Module Screw Sizes and Lengths	• 2.4mm locking standard screws with lengths 6mm to 22mm • 2.4mm locking Auto-Drive™ screws with lengths of 6mm to 8mm	• 2.4mm locking standard screws with lengths 6mm to 22mm • 2.4mm locking Auto-Drive™ screws with lengths of 6mm to 8mm
Instruments	The instruments include drill bits, plate bending pliers, plate holding forceps, plate cutters, drill guides, cannulae, taps, countersinks, and	The instruments include drill bits, plate bending pliers, plate holding forceps, plate cutters, drill guides, cannulae, taps, countersinks, and

Comparison Table Modular Locking Fixation Mandible Module		
System / Device Name	***OSTEOMED ICON Modular Locking Fixation Mandible Module Reconstruction Plates***	***OSTEOMED Modular Locking Fixation System Mandible Module Reconstruction Plates***
	screwdrivers to facilitate the placement of screws and modification of plates.	screwdrivers to facilitate the placement of screws and modification of plates.
Technology	Locking Plates and Screws to fixate bone	Locking Plates and Screws to fixate bone
Principles of Operation	Angulated Locking for Rigid Fixation	Angulated Locking for Rigid Fixation
Features	Various Plates and Screws	Various Plates and Screws
Plates (shape)	Variety of shapes and sizes (e.g., straight, angled right, angled left, contoured with various size holes). Plates can be modified/contoured and cut to length	Variety of shapes and sizes (e.g., straight, angled right, angled left, contoured with various size holes). Plates can be modified/contoured and cut to length
Plate holes	Angled Locking/Locking	Angled Locking/Locking

The basis of substantial equivalence of the OsteoMed ICON Modular Locking Fixation System to the OsteoMed Modular Locking Fixation System, K080694, is based on the similarities in design, technology, material, function, sterilization, and intended use. OsteoMed believes that the non-clinical tests demonstrate that the device is substantially equivalent to the predicate devices.

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