510(k) Summary

FEB 24 2014

Submitter Information:

OsteoMed
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Contact Person: Blesson Abraham

Date Prepared: November 27, 2013

Device Information:

Proprietary/Trade Name: ***OSTEOMED*** Ankle Plating System
Common Name: Bone Plating System

Classification Name:

- Regulation Number:
  - 21 CFR 888.3030
  - 21 CFR 888.3040
- Regulation Name:
  - Single/multiple component metallic bone fixation appliances and accessories (Plate, Fixation, Bone)
  - Smooth or threaded metallic bone fixation fastener (Screw, Fixation, Bone: Pin, Fixation, Smooth)
- Product Code:
  - HRS
  - HWC

Device Class: II

Predicate Devices:

Synthes Dynamic Compression Locking Plating System (Synthes One-Third Tubular DCL Plate), K011335
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (**21CFR 888.3030, Product Code HRS**)
Device Class: **II**

OsteoMed Foot Plating System, K091614
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (**21CFR 888.3030, Product Code HRS**)
Device Class: **II**

OsteoMed Super Screw 3.5mm, K954330
Classification Name: Smooth or threaded metallic bone fixation fastener (**21CFR 888.3040, Product Code HWC**)
Device Class: **II**

Merete Locking Bone Plate System III, K120787
Classification Name: Single/multiple component metallic bone fixation appliances and accessories (**21CFR 888.3030, Product Code HRS**)
Smooth or threaded metallic bone fixation fastener (**21CFR 888.3040, Product Code HWC**)
Device Class: **II**

Device Description:

The ***OSTEOMED ExtremiLOCK Ankle Plating System*** is a comprehensive ankle fracture system intended to provide solutions for various bony fractures, including simple to complex fractures of the distal tibia and fibula. The plates are provided in a variety of shapes and sizes, offering surgeons compression, non-locking and locking hole designs. The *ExtremiLOCK Ankle Plating System* includes angulated locking screws and standard non-locking screws as well as K-wires. Surgical instrumentation is provided to facilitate insertion, modification and/or removal of implants.

The implants of the OsteoMed ExtremiLOCK Ankle Plating System are made from Titanium (ASTM F-67) or Titanium alloy (ASTM F-136). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/medical grade polymer.

Intended Use:

The ***OsteoMed ExtremiLOCK Ankle Plating System*** is intended for fixation of fractures, arthrodesis, osteotomies, and non-unions of the tibia and fibula. The ExtremiLOCK Ankle Plating System implants are intended for single use only.

The 1/3 tubular plates, hook plates, screws, and washers are also intended for use in trauma, general surgery, and reconstructive procedures of bones appropriate for the size of the device.

The ***OsteoMed ExtremiLOCK Ankle Plating System*** can be used for adult and pediatric patients.

Technological Characteristics:

The OsteoMed ExtremiLOCK Ankle Plating System is recommended for fixation/reconstruction of distal tibia and fibula, or other bones appropriate for the size of the device.

ExtremiLOCK implants are manufactured from Titanium (ASTM F-67) or Titanium alloy (ASTM F-136), the same materials used in the manufacture of the predicate devices. These materials are biocompatible.

Performance / Clinical Data:

The OsteoMed ExtremiLOCK Ankle Plating System was compared to the Synthes One-Third Tubular DCL Plate, K011335, the OsteoMed Foot Plating System, K091614, the OsteoMed Super Screw 3.5mm, K954330, and the Merete Locking Bone Plate System III, K120787. The ExtremiLOCK Ankle implants underwent verification evaluation (pull-out, torque and bending tests) to ensure that the design features met the required mechanical strength criteria for their intended use. The intended use of the OsteoMed ExtremiLOCK Ankle implants is similar to the Synthes One-Third Tubular DCL Plate, the OsteoMed Foot Plating System, the OsteoMed Super Screw 3.5mm, and the Merete Locking Bone Plate System III.

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 and dimensional 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, function, performance, design, technology and operational principles to the Synthes One-Third Tubular DCL Plate (K011335), the OsteoMed Foot Plating System (K091614), the OsteoMed Super Screw 3.5mm (K954330), and similarities in intended use, material, and function to the Merete Locking Bone Plate System III (K120787).

Substantial equivalence was shown through the pullout test, torque test, and bending test to the predicate devices (the Synthes One-Third Tubular Plate, the OsteoMed Foot Plating System, and the OsteoMed Super Screw 3.5mm). The intended use, design, technology and operational principles are similar between the subject and predicates (the Synthes One-Third Tubular Plate, the OsteoMed Foot Plating System, the OsteoMed Super Screw 3.5mm, and Merete Locking Bone Plate System III), and therefore OsteoMed believes that the ***OSTEOMED ExtremiLOCK Ankle Plating System*** does not raise any new safety or effectiveness issues.

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

February 24, 2014

OsteoMed
Mr. Blesson Abraham
Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

Re: K133691
Trade/Device Name: OsteoMed ExtremiLOCK Ankle Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: November 27, 2013
Received: December 2, 2013

Dear Mr. Abraham:

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,

Vincent J. Devlin -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133691 (pg 1/1)

Device Name: OsteoMed ExtremiLOCK Ankle Plating System

Indications for Use:

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The 1/3 tubular plates, hook plates, screws, and washers are also intended for use in trauma, general surgery, and reconstructive procedures of bones appropriate for the size of the device.

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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)

Elizabeth L. Frank -S

Division of Orthopedic Devices