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SEP 10 2009

510(k) Summary

Device Proprietary Name:	OsteoMed Foot Plate and Screw Rigid Fixation System
Device Common Name:	OsteoMed Foot Plating System
Classification Name:	21 CFR § 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Product Code:	HRS, HWC
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4781 Fax: (972) 677-4778
Contact Person:	Alma Relja, RAC
Date Prepared:	June 1, 2009

Summary:

This submission describes the OsteoMed Foot Plating System consisting of various shape and sizes plates featuring compression, locking, elongated or compression elongated holes, angulated locking, non-locking and cannulated screws, implantable K-wires, washers, and appropriate instrumentation. The OsteoMed Foot Plating System is indicated for use in trauma, general surgery, and reconstructive procedures of the foot, ankle or other bones appropriate for the size of the device. All implants are intended for single use only. Surgical instrumentation is provided to facilitate modification, insertion, and removal of implants.

The system contains several modules based on the size of the device and application site such as fixation/reconstruction of small fragment bones, forefoot, mid-foot, rear-foot, ankle, , or other bones appropriate for the size of the device.

The implants are made of Titanium (ASTM F-67, ASTM F-136, or ASTM F-1472) or Stainless Steel (ASTM F-138 or ASTM F-139). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade polymers.

Equivalence for this system is based on similarities in intended use, material, design and operational principle to the predicate devices listed in this submission. Also, note that some sections of this system could have been letter to file based on the OsteoMed previously cleared submissions.

Due to the similarity of materials and design to both pre-enactment and post-enactment devices we believe that the OsteoMed Foot Plating System does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

SEP 1 0 2009

Osteomed L.P.
% Ms. Alma Relja, RAC
Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

Re: K091614
Trade/Device Name: OsteoMed Foot Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: September 3, 2009
Received: September 4, 2009

Dear Ms. Relja:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K091614

Device Name: OsteoMed Foot Plating System

Indications for Use:

The OsteoMed Foot Plating System is indicated for use in trauma, general surgery, and reconstructive procedures of the foot, ankle or other bones appropriate for the size of the device.

The OsteoMed Foot Plating System implants 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)

for MKR

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091614

(Posted November 13, 2003)