K120015 #1/2

510(k) Summary

APR 2 4 2012

Date Prepared:	April 18, 2012
Name of Submitter:	OsteoMed 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4781 Fax: (972) 677-4778
Contact Person:	Suzanne Cheang
Device Proprietary Name:	OsteoMed Wrist Plating System
Common Name:	Wrist Plating System
Classification Name:	21 CFR § 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Product Code:	HRS, HWC

Device Description:

The OsteoMed Wrist Plating System is a rigid fixation and fusion system consisting of plates and screws in various configurations along with the appropriate instrumentation to facilitate modification, implantation, or removal of the implants. Plates are anatomically pre-contoured in various shapes and sizes. Screws are provided with variable angle locking or non-locking head in various lengths. These screws are either solid core or cannulated and can be used with or without plates.

Indication for Use:

OsteoMed Wrist Plating System is intended for fracture fixation, fusion and osteotomies of wrist and other bones appropriate for the size of the device. It is intended for use in trauma, general surgery and reconstructive procedures.

OsteoMed Wrist Plating System implants are intended for single use only.

Substantial Equivalence:

K090522: OsteoMed Hand Plating System
K091614: OsteoMed Foot Plating System
K924018: M3 Lag Screw Fixation System

K120015 #2/2

K040022: Stryker Leibinger Universal Distal Radius System
K051735: PERI-LOC Periarticular Locked Plating System
K083694: Synthes 2.4mm VA-LCP Two Column Volar Distal Radius Plate
K091644: Synthes (USA) 2.4mm LCP Volar Column Distal Radius Plates
K042355: Synthes (USA) LCP Wrist Fusion Plates
K052248: Dorsal Nail Plate, Anatomical
K062863: OsteoMed Extended 2.0/2.4 Cannulated Screw System

Plates and screws are supplied in a variety of configurations. The plates and screws are made of titanium alloy (ASTM F136). K-wires are made of titanium alloy (ASTM F136) or stainless steel (ASTM F138). The instrumentation is made from various grades of stainless steel, anodized aluminum, and/or medical grade polymers. There are no technological characteristics that raise new issues of safety or effectiveness.

Analyses of plate and screw strength were conducted to compare the OsteoMed Wrist Plating system components to predicate devices.

Equivalence for OsteoMed Wrist Plating system is based on similarities in intended use, design and operational principle to the referenced predicates. Based on the similarities, we believe that the OsteoMed Wrist 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 Room --WO66-G609
Silver Spring, MD 20993-0002

OsteoMed
% Ms. Suzanne Cheang
Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

APR 2 4 2012

Re: K120015
Trade/Device Name: OsteoMed Wrist 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: March 1, 2012
Received: March 2, 2012

Dear Ms. Cheang:

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 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 (301) 796-7100 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): K120015

Device Name: OsteoMed Wrist Plating System

Indications for Use:

OsteoMed Wrist Plating System is intended for fracture fixation, fusion and osteotomies of wrist and other bones appropriate for the size of the device. It is intended for use in trauma, general surgery and reconstructive procedures.

OsteoMed Wrist 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)

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

510(k) Number K120015