K090522 1/1

# 510(k) Summary

JUL - 2 2009

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| Device Proprietary Name: | OsteoMed Hand Plate and Screw Fixation System |
| Device Common Name: | OsteoMed Hand Plating System |
| Classification Name: | 21 CFR § 888.3030: Single/multiple component metallic bone fixation appliances and accessories<br>21 CFR § 888.3040: Smooth or threaded metallic bone fixation fastener |
| Product Code: | HRS, HWC |
| Name of Submitter: | OsteoMed L. P.<br>3885 Arapaho Road<br>Addison, Texas 75001<br>Phone: (972) 677-4781 Fax: (972) 677-4778 |
| Contact Person: | Alma Relja, RAC |
| Date Prepared: | February 23, 2009 |

Summary:
This submission describes the OsteoMed Hand Plating System intended for use in trauma, general surgery and reconstructive procedures of the hand, wrist, or other bones appropriate for the size of the device. The OsteoMed Hand Plating System implants are intended for single use only.

The OsteoMed Hand Plating System is a rigid fixation system consisting of plates and screws in various configurations. Plates are provided in a variety of shapes and sizes, and offer surgeons compression and locking hole designs. The Hand Plating System includes angulated locking, non-locking, lag, and cannulated screws as well as a buttress pin and K-wire implants. Surgical instrumentation is provided to facilitate modification, insertion, and removal of implants.
The implants are made of Titanium (ASTM F-67 or ASTM F-136) 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 OsteoMed M3 System (K911936/Addendum K924138/K030448), Synthes Modular Mini Fragment LCP System (K06349) and Synthes Stainless Steel Modular Hand System (K030310), SBI Hand Fixation System (K050462), and Stryker Small Bone Plating System (K061497). Furthermore, OsteoMed also notes 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 Hand Plating System does not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2009

OsteoMed L.P.
% Ms. Alma Relja
3885 Arapaho Road
Addison, Texas 75001

Re: K090522
Trade/Device Name: OsteoMed Hand 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: June 25, 2009
Received: June 30, 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/cdrh/comp/ 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

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): K090522

Device Name: OsteoMed Hand Plating System

Indications for Use:

OsteoMed Hand Plating System is intended for use in trauma, general surgery and reconstructive procedures of the hand, wrist, or other bones appropriate for the size of the device.

The OsteoMed Hand 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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K090522



*(Posted November 13, 2003)*