K111419 #1/2

OCT - 7 2011

510(k) Summary

Date Prepared:	10/06/11
Name of Submitter:	OsteoMed L. P. 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4781 Fax: (972) 677-4778
Contact Person:	Suzanne Cheang
Device Proprietary Name:	OsteoMed Hand Fusion System
Common Name:	Hand Fusion System
Classification Name:	21 CFR § 888.3030: Single/multiple component metallic bone fixation appliances and accessories
Product Code:	HRS, HWC

Device Description:

The OsteoMed Hand Fusion System consists of plates, fusion screws and surgical instruments. Plates and fusion screws are provided in various sizes. The implants are made of Titanium (ASTM F-67 or ASTM F-136) or Stainless Steel (ASTM F-138 or ASTM F-139).

Surgical instrumentation is provided to facilitate modification, insertion, and removal of implants. These instruments are made from various grades of stainless steel, anodized aluminum, and/or medical grade polymers.

Indication for Use:

OsteoMed Hand Fusion System is intended for use in bone fusion and arthrodesis of phalanges and metacarpals. It is intended for use in trauma, general surgery and reconstructive procedure.

The OsteoMed Hand Fusion System implants are intended for single use only.

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Substantial Equivalence Information:

K063298 - OsteoMed Cannulated Headless Screw System
K090522 - OsteoMed Hand Plating System
K063049 – Synthes Modular Mini Fragment LCP System
K030310 – Synthes Stainless Steel Modular Hand System

The OsteoMed Hand Fusion System shares dimensional and material characteristics with the OsteoMed Hand Plating System, listed as a predicate above. An engineering analysis of plate strength was conducted to compare the Fusion plate to the predicate device. Calculations based on cross sectional area and plate material showed that the Fusion plate is able to withstand more load than the predicate device. Mechanical strength testing of the Fusion screw and the Fusion plate and screw construct was performed to further prove substantial equivalence. Test results show that the factor of safety (the ratio of failure torque to insertion torque) of the Fusion screws is equivalent to the factor of safety of the OsteoMed Headless Screws, a predicate listed above. Test results also show the pullout strength of the Fusion screws is equivalent to the pullout strength of the predicate device. Finally, testing of the plate and screw construct showed locking screw engaged with the Fusion plate hole is substantially equivalent to the predicate devices.

Based upon similarities in the operational principle, design features, material and intended use to the predicate devices, the safety and effectiveness of the OsteoMed Hand Fusion System is substantially equivalent to the predicate devices listed above.

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

OCT - 7 2011

OsteoMed L.P.
% Ms. Suzanne Cheang
3885 Arapaho Road
Addison, Texas 75001

Re: K111419
Trade/Device Name: OsteoMed Hand Fusion 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: September 27, 2011
Received: September 28, 2011

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): K111419

Device Name: OsteoMed Hand Fusion System

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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)

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

510(k) Number K111419