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

May 19, 2016

OsteoMed
Ms. Kathryn Jayne
Senior Specialist, Regulatory Affairs
3885 Arapaho Road
Addison, Texas 75001

Re: K161041
Trade/Device Name: OsteoMed ExtremiLOCK 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: April 14, 2016
Received: April 15, 2016

Dear Ms. Jayne:

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 Parts 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 Industry and Consumer Education 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 Industry and Consumer Education 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 -S

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): K161041

Device Name: OsteoMed ExtremiLOCK Wrist Plating System

Indications for Use:

The OsteoMed ExtremiLOCK Wrist Plating System is indicated 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 ExtremiLOCK 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)

510(k) Summary

Submitter Information	OsteoMed 3885 Arapaho Road Addison, Texas 75001 Phone: (972) 677-4600 Fax: (972) 677-4601
Contact Person	Ms. Kathryn Jayne
Date Prepared	May 13, 2016
Proprietary Name:	***OSTEOMED EXTREMILOCK WRIST PLATING SYSTEM***
Common Name:	Wrist Fixation System
Classification Names:	21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Product Codes:	HRS, HWC
Class:	II
Predicate:	**OsteoMed ExtremiLOCK Wrist Plating System, K152145**
Classification Names:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories; 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Product Code:	HRS, HWC
Class:	II
Device Description	The OsteoMed ExtremiLOCK 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 and implantation. Plates are anatomically pre-contoured in various shapes and sizes. Screws are provided with variable angle locking and non-locking heads and are either fully threaded or partially threaded in various lengths. These screws are either solid core or cannulated and can be used with or without plates. The system also contains K-wire implants. The implants of the OsteoMed ExtremiLOCK Wrist Plating System are made from Titanium per ASTM F-67 (Plates), Titanium Alloy per ASTM F-136 (plates, screws and washer), and Stainless Steel per ASTM F-138(K-wires). The dimensional modifications to the screws include the addition of flutes (for screw lengths ≤ 16mm), tapered tip, decrease in thread pitch, and extending threads to the partially threaded locking screw. The rest

	of the system has already been cleared through OsteoMed wrist predicate 510(k) K152145.
Indications for use/ Intended Use	The OsteoMed ExtremiLOCK Wrist Plating System is indicated 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 ExtremiLOCK Wrist Plating System implants are intended for single use only.
Performance Characteristics & Testing & Clinical	**Performance**: Verification testing was conducted to assess the performance of the screws (subject device). The verification testing confirmed the screws met minimum requirements as specified in ASTM F543 or performed equal or better compared to the predicate devices. The screws met the mechanical strength criteria for the intended use. Performance equivalence was shown through the verification comparison to the predicate devices. **Clinical Testing** is not required to support substantial equivalence.
Substantial Equivalence	The basis of substantial equivalence for this device, **OsteoMed ExtremiLOCK Wrist Plating System**, is based on similarities in indications for use, material, function, performance, design, technology, shelf life, sterilization, and operational principles to the OsteoMed predicate device. Performance comparisons were performed which verified that the modified screws met required mechanical strength criteria for their intended use compared to the predicate devices listed in this summary. OsteoMed has shown that the non-clinical tests demonstrate that the subject device is as safe and effective as the predicate device.