



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

Osteomed Corp.
Mrs. Piedad Peña
Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

July 15, 2015

Re: K151021

Trade/Device Name: Osteomed Cannulated Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: June 16, 2015
Received: June 17, 2015

Dear Mrs. Peña:

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 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" (21 CFR 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): K151021 (page 1/1)

Device Name: OsteoMed Cannulated Screw System

Indications for Use:

The OsteoMed Cannulated Screw System is indicated for bone fixation of hand and foot following trauma or osteotomy. Screws and washers 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)



Special 510(k) Summary

Name of Submitter: OsteoMed
3885 Arapaho Road
Addison, Texas 75001
Phone: (972) 677-4600
Fax: (972) 677-4601

Contact Person: Piedad Peña

Date Prepared: July 8, 2015

Device Proprietary Name: OsteoMed Cannulated Screw System

Device Common Name: Cannulated bone screws, washers and associated instruments

Classification Name: 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener

Product Code: HWC

Predicate Device: OsteoMed Extended 2.0/2.4 Cannulated Screw System, K062863

Classification Name: Smooth or threaded metallic fixation fastener (21CFR 888.3040, Product Code HWC)
Device Class: II

Reference Device: OsteoMed Super Screw System, K954330

Classification Name: Smooth or threaded metallic fixation fastener (21CFR 888.3040, Product Code HWC)
Device Class: II

Summary:

Device Description:

The *OSTEOMED Cannulated Screw System* is comprised of screws and washers used for bone fixation of the hand and foot following trauma or osteotomy. The System features cannulated screws in the following dimensions:

- 2.0mm screw diameter – 6mm to 42mm screw length;
- 2.4mm screw diameter – 6mm to 52mm screw length;
- 3.0mm screw diameter – 10mm to 40mm screw length;
- 3.5mm screw diameter – 12mm to 52mm screw length;
- 4.0mm screw diameter – 12mm to 52mm screw length;
- 5.5mm screw diameter – 12mm to 52mm screw length;
- 6.5mm screw diameter – 20mm to 120mm screw length;
- 8.0mm screw diameter – 30mm to 140mm screw length;



The implants (screws and washers) of the OsteoMed Cannulated Screw System are made from Titanium alloy (ASTM F-136). Modifications to screws and washer of the subject system include redesign of the 4.0mm cannulated screw to increase the strength of the lag portion and addition of a 3.0mm diameter cannulated screw and washer.

The system instruments include depth gauges, screw drivers, drills, countersinks, k-wires, and preparation instruments to facilitate the placement of screws. The instrumentation is made from various grades of stainless steel, anodized aluminum, and/medical grade polymer.

Indications for Use:

The OsteoMed Cannulated Screw System is indicated for bone fixation of hand and foot following trauma or osteotomy. Screws and washers are intended for single use only.

Technological Characteristics:

The OsteoMed Cannulated Screw System is available in a variety of sizes and is recommended for bone fixation in the hand and foot.

Cannulated Screw System implants (screws and washers) are manufactured from Titanium alloy (ASTM F-136), the same materials used in the manufacture of the predicate devices. This material is biocompatible.

Performance/Clinical Data:

The OsteoMed Cannulated Screw System was compared to the reference device, OsteoMed Super Screw System (K954330), and predicate device, OsteoMed Extended 2.0/2.4 Cannulated Screw System (K062863). The 3.0mm and 4.0mm cannulated screws underwent verification evaluation to ensure that the design features met the required mechanical strength criteria for their intended use. The intended use of the OsteoMed Cannulated Screw System is the same as OsteoMed Extended 2.0/2.4 Cannulated Screw System (K062863).

Performance equivalence was shown through the verification comparison to the predicate device and reference device.

Clinical testing is not required to support substantial equivalence.

Substantial Equivalence:

The basis of substantial equivalence for this device, OsteoMed Cannulated Screw System, is based on similarities in intended use, material, function, performance, design, technology, sterilization, and operational principles to the predicate device, OsteoMed Extended 2.0/2.4 Cannulated Screw System (K062863). A performance comparison was performed and verified that the cannulated screws met required mechanical strength criteria for their intended use compared to the legally marketed predicate device and reference device listed in this summary. OsteoMed believes that the non-clinical tests demonstrate that the device is as safe, and effective as the predicate device.