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

April 4, 2017

OsteoMed LLC
Kathryn Jayne
Senior Specialist, Regulatory Affairs
3885 Arapaho Rd
Addison, Texas 75001

Re: K163303
Trade/Device Name: OsteoMed ExtremiFix Mid And Large Screw System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: March 8, 2017
Received: March 10, 2017

Dear Ms. Kathryn 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 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,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163303

Device Name
OsteoMed ExtremiFix Mid & Large Screw System

Indications for Use *(Describe)*
The OsteoMed ExtremiFix Mid & Large Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, and fracture fixation of foot, ankle, and long bones (upper and lower extremity). The screws are intended for single use only. The system drills and guide wires are single use instruments.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

I. SUBMITTER

OsteoMed
3885 Arapaho Rd.
Addison, TX 75001

Phone: 972-677-4766
Fax: 800-390-2620
Email: kjayne@osteomed.com

Contact: Kathryn Jayne
Phone: 972-677-4766
Fax: 800-390-2620
Email: kjayne@osteomed.com

Alternate Contact: Alicia Hemphill
Phone: 972-677-4786
Email: ahemphill@osteomed.com

Date Prepared: March 28, 2017

II. DEVICE

Name of the Device:	***OsteoMed ExtremiFix Mid and Large Screw System***
Common or Usual Name:	Bone Fixation Screw System
Classification Name:	Smooth or threaded metallic bone fixation fastener
Regulation:	888.3040
Regulatory Class:	II
Product Code:	HWC, HTN

III. PREDICATE DEVICE

Primary Predicate:	OsteoMed Headless Cannulated Screw (K063298)
Additional Predicate:	OsteoMed Cannulated Screw System (K151021)
Additional Predicate:	Synthes Sterile 4.5 mm Cannulated Screws (K963172)
Additional Predicate:	Smith & Nephew Richards, Inc. Screw (K951389)
Additional Predicate:	OsteoMed Super Screw System (K954330)

IV. DEVICE DESCRIPTION

The OsteoMed ExtremiFix Mid & Large Screw System is a rigid fixation system consisting of screws in both cannulated and solid versions, all of which are available in various overall and distal thread lengths to accommodate specific patient anatomies. The headed and headless compression screws are made of biocompatible Ti 6-Al 4-V Titanium Alloy. Longer sizes of the single-use only implants are provided individually sterile packed, while the majority of screws and all instruments are provided in modules to allow for customization specific to the surgical indication. The system includes washers for use with 4.5mm, 5.5mm, 6.5mm and 7.0mm headed screws. The washers are made of biocompatible Titanium Alloy. The OsteoMed ExtremiFix Mid & Large Screw System is sterilized in a sterilization tray which is available from OsteoMed.

The subject device is intended for use in a healthcare facility/hospital for use by a clinician. It is a prescription device.

V. INDICATIONS FOR USE

The OSTEOMED ExtremiFix Mid & Large Screw System is indicated for use in bone reconstruction, osteotomy, arthrodesis, and fracture fixation of foot, ankle, and long bones (upper and lower extremity). The screws are intended for single use only. The system drills and guide wires are single use instruments.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Performance Characteristics & Testing & Clinical

Verification testing was conducted to ensure the subject screws performed equal or better compared to the predicate devices. The subject screws were also tested against the Synthes predicate reference device to ensure the design features met the required mechanical strength criteria for their intended use. The screws with the dual lead technology underwent verification evaluation to ensure the new design features met the mechanical strength criteria for the intended use. The screws were compared to their respective predicate.

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, the OsteoMed ExtremiFix Mid and Large Screw System, is based on similarities in indications for use, intended use, material, function, performance, design, technology, sterilization, and operational principles to the OsteoMed predicates and Synthes predicate. Performance comparisons were performed which verified that the new screw system met required mechanical strength criteria for their intended use compared to the legally marketed predicate devices listed in this summary. OsteoMed has shown that the non-clinical tests demonstrate that the devices are as safe and as effective as the predicate devices.

System/Device Name	Subject Device **OsteoMed ExtremiFix Mid and Large Screw System** 	Primary Predicate **OsteoMed Headless Cannulated Screw System** 	Secondary Predicate **OsteoMed Cannulated Screw System** 	Reference Predicate **Synthes Sterile 4.5mm Cannulated Screws** 
510(k) Number	**Pending**	**K063298**	**K151021**	**K963172**
Regulation No.	888.3040	888.3040	888.3040	888.3040
Product Code	HWC, HTN	HWC	HWC	HWC
Device Class	II	II	II	II
Regulatory Panel	Orthopedic	Orthopedic	Orthopedic	Orthopedic
Indication for Use / Intended Use	Fracture fixation, reconstruction, osteotomy, and arthrodesis procedures of foot, ankle, and long bones (upper and lower extremity).	Bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device. Screws are intended for single use only.	Bone Fixation of hand and foot following trauma or osteotomy. Screws and washers are intended for single use only.	Fracture fixation of long bones and long bone fragments.
Material	Titanium Alloy - Ti 6Al-4V (ASTM F136)	Titanium Alloy - Ti 6Al-4V (ASTM F136)	Titanium Alloy - Ti 6Al-4V (ASTM F136)	Titanium Alloy - Ti 6Al-4V and Stainless Steel
Technology	Screws to fixate Bone	Screws to fixate Bone	Screws to Fixate Bone	Screws to Fixate Bone
Operating Principles	Rigid fixation	Rigid fixation	Rigid fixation	Rigid fixation
Insertion Material	Bone	Bone	Bone	Bone
Screw Length (mm)	20mm - 180mm	10mm -120mm	10mm -140mm	20mm - 80mm
Screw Diameter	4.5mm - 7.0mm	2.0mm - 6.5mm	3.0mm -8.0mm	4.0 mm
Head Type	Hexalobe	Trilobe	Cruciform Hex	Hex
Headless (HL)	Yes	Yes	No	No
Headed (HD)	Yes	No	Yes	Yes
Cannulated	Yes	Yes	Yes	Yes
Solid	Yes	No	No	No
Short Thread (ST)	Yes	Yes	Yes	Yes

System/Device Name		Subject Device **OsteoMed ExtremiFix Mid and Large Screw System** 	Primary Predicate **OsteoMed Headless Cannulated Screw System** 	Secondary Predicate **OsteoMed Cannulated Screw System** 	Reference Predicate **Synthes Sterile 4.5mm Cannulated Screws** 
510(k) Number		**Pending**	**K063298**	**K151021**	**K963172**
Long Thread (LT)		Yes	Yes	No	No
Full Thread (FT)		Yes	No	No	Yes
Screw Type		HL Cannulated ST & LT HD Cannulated ST, LT,& FT Headed Solid ST	Headless Cannulated	Headed Cannulated	Headed Cannulated
Double-Lead		Yes	No	No	No
Low Profile Heads		Yes	Yes	Yes	TBD
Self-Drilling		Yes	Yes	Yes	Yes
Self-Tapping		Yes	Yes	Yes	Yes
Lag		Yes	Yes	Yes	Yes
Reverse Cutting Flutes		Yes	No	No	Yes
Washers	Availability	Yes	No	Yes	Yes
	Part Numbers	316-0325 316-0326	N/A	316-0225	419.91
	Screw Size	4.5 - 5.5 mm	N/A	3.0 mm	4.5mm
	Thickness	1.0 mm	N/A	1.0 mm	N/A
	Outer Diameter	10.0 -11.0 mm	N/A	12.4 mm	10 mm
	Material	Titanium Alloy	N/A	Titanium Alloy	CPTi
Instrumentation		Single Use and Re-usable Preparation Instruments	Single Use and Re-usable Preparation Instruments	Single Use and Re-usable Preparation Instruments	Single Use and Re-usable Preparation Instruments
Instrumentation Materials		Stainless Steel, Anodized Aluminum, Medical grade polymer	Stainless Steel, Anodized Aluminum, Medical grade plastic	Stainless Steel, Anodized Aluminum, Medical grade polymer	Stainless Steel

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility

The biocompatibility evaluation for the device was conducted in accordance with the FDA Guidance Document, issued on June 16, 2016, *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1:*

Evaluation and testing within a risk management process" – Guidance for Industry and Food and Drug Administration Staff.

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Sub-chronic toxicity
- Genotoxicity
- Implantation
- Pyrogen testing

The instruments are considered tissue contacting for a duration of less than 24 hours while the implants are considered permanent implants. The Titanium alloy implant material conforms to ASTM F-136 for chemical composition.

Electrical Safety and Electromagnetic Compatibility (EMC)

The OsteoMed ExtremiFix Mid & Large Screw System is not an active device; therefore, Electrical Safety and Electromagnetic Compatibility (EMC) testing is not applicable.

Software Verification and Validation Testing

The OsteoMed ExtremiFix Mid & Large Screw System does not contain software; therefore, Software Verification and Validation Testing is not applicable.

Bench Testing

The following bench evaluations were conducted:

- Self-Tapping Force
- Safety Factor (Failure Torque / Insertion Torque)
- Pullout Force
- Torsional Strength (Solid Screws Only)
- Bending Strength
- Sterilization Validation
- Endotoxin Testing

Animal Study

No animal studies were performed to demonstrate safety and efficacy.

Clinical Studies

No clinical studies were performed to demonstrate safety and efficacy.

VIII. CONCLUSIONS

The basis of substantial equivalence for the proposed device is based on similarities in indications for use, material, function, performance, design, technology, sterilizations, and operating principles. The non-clinical data support the substantial equivalence and demonstrates that the device should perform as intended in the specified use conditions.

(End of Summary)