October 29, 2020

OsteoMed LLC
Andrew Johnson
Senior Regulatory Affairs Specialist
3885 Arapaho Road
Addison, Texas 75001

Re: K202105
Trade/Device Name: OsteoMed ExtremiFix Mini & Small System Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: July 28, 2020
Received: July 31, 2020

Dear Andrew Johnson:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Kapil Panguluri, PhD
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202105

Device Name

OsteoMed ExtremiFix Mini & Small System Tray

Indications for Use *(Describe)*

The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (pre- vacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.

Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.

Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:
Method: Steam Cycle
Pre-Vacuum Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 50 minutes

Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a rigid container configuration:
Method: Steam Cycle
Pre-Vacuum Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

K202105 510(k) SUMMARY

I. SUBMITTER

OsteoMed

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Addison, TX 75001 USA

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Fax: 972-677-4601

Email: djohnson@osteomed.com

Contact Person: Drew Johnson

Date Prepared: 7/28/2020

II. DEVICE

Name of the Device: OsteoMed ExtremiFix Mini & Small System Tray
Common or Usual Name: Sterilization Tray
Classification Name: Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation: 880.6850
Regulatory Class: II
Product Code: KCT

III. PREDICATE DEVICE

Predicate Device: OsteoMed MMF Sterilization Tray (K173391)

Reference Device: NuVasive Sterilization Tray (K143579)

IV. DEVICE DESCRIPTION

The OsteoMed ExtremiFix Mini & Small System Tray is composed of anodized and non-anodized aluminum, stainless steel, silicone, polyethylene terephthalate (Mylar), polyphenylsulfone (Radel), polyamide 11 (nylon), and ZEUS Perfluoroalkoxy (PFA), which are common tray materials, and is used to enclose, protect, and organize OsteoMed ExtremiFix Mini & Small System implants and surgical instruments. This is a product specific sterilization storage system tray (only for use with the OsteoMed ExtremiFix Mini & Small System) that is intended to provide storage for the OsteoMed ExtremiFix screws and accessories during sterilization, storage, and transportation within the hospital environment.

The OsteoMed ExtremiFix Mini & Small System Tray is a single sterilization storage system that is comprised of one outer case (base + lid), two screw modules

(any two of the four sizes), and two trays (handle tray + instrument tray). The trays are perforated to allow for steam sterilization. An FDA-cleared wrap or FDA-cleared rigid sterilization container must be used for sterilization and to maintain the sterility of the contents. The OsteoMed ExtremiFix Mini & Small SystemTray is designed to be used with standard autoclaves used in hospitals and healthcare facilities. As such, the OsteoMed ExtremiFix Mini & Small System Tray is effective for containing the system devices during sterilization and have been designed to withstand repeated steam sterilization cycles.

V. INDICATIONS FOR USE

The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container.

Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray.

Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration:
Method: Steam Cycle
Pre-Vacuum Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 50 minutes

Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a rigid container configuration:
Method: Steam Cycle
Pre-Vacuum Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Provided in the table below is the OsteoMed ExtremiFix Mini & Small System Tray and the comparison with the predicate.

Characteristics	Subject Device: OsteoMed ExtremiFix Mini & Small System Tray	Predicate Device: OsteoMed QuickFix Hybrid MMF Sterilization Tray (K173391)	Comparison
Product Code	KCT	KCT	Same
21 CFR	888.685	888.685	Same
System Components	Base, lid, screw modules, instrument trays	Base, lid, locking latch	Similar
Material Composition	Aluminum, stainless steel, silicone, polyethylene terephthalate, nylon, polyphenylsulfone, ZEUS Perfluoroalkoxy	Aluminum	Similar
Physical Properties	Evenly distributed perforated hole pattern	Evenly distributed perforated hole pattern	Same
Configurations/Dimensions (L x W x H) in.	Outer case: 17.6 x 9.5 x 4.1 Screw modules: 8.1 x 6.1 x 3.3 Instrument trays: 9.2 x 3.3 x 1.6	Rectangle base with lid: 9.5 x 5.0 x 1.5	Similar
Sterilant Penetration	Sterilant (steam) penetration through perforations in tray	Sterilant (steam) penetration through perforations in tray	Same
Sterilization method	Steam	Steam	Same
Sterilization cycle	Pre-vacuum	Pre-vacuum	Same
Exposure temperature	270°F (132°C)	270°F (132°C)	Same
Exposure time	4 minutes	4 minutes	Same
Dry time	30 minutes (rigid container) 50 minutes (wrapped)	30 minutes	Similar
Reusable	Yes	Yes	Same
Vent to Volume Ratio	Outer case: 0.231 in^2/in^3 Module: 0.260 in^2/in^3	Base/lid: 0.050 in^2/in^3	Similar
Worse Case Lumen	T7 driver long: Ø0.038, L = 0.371" (1 ea.) T10 driver long: Ø0.050, length 5" (1 ea.) 2.0mm module screw hole: Ø0.092, length 0.325" (126 ea.)	Base steam hole: Ø0.094, length 1.075" (1 ea.) Driver sleeve: Ø0.115, length 0.680" Driver handle: blind hole Ø0.111, depth 1.173"	Similar

	2.4mm module screw hole: Ø0.105, length 0.325” (150 ea.) 3.0mm module screw hole: Ø0.130, length 0.325” (96 ea.) 4.0mm module screw hole: Ø0.165, length 0.325” (108 ea.)		
Indications for Use	The OsteoMed Mini & Small System Tray is intended to contain Mini and Small implants and surgical instruments for sterilization, storage and handling. The OsteoMed Mini & Small System Tray is suitable for dynamic air removal (prevacuum) steam sterilization methods. The system tray is not intended to maintain sterility; it is intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. The System Tray may also be used in conjunction with a legally marketed rigid container. Sterilization validation was performed utilizing the ExtremiFix Mini & Small Cannulated Screw System implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 14.1 lbs. in the sterilization system tray. Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a wrapped configuration: Validated sterilization parameters for OsteoMed	The OsteoMed QuickFix Hybrid MMF Sterilization Tray is intended to contain OsteoMed QuickFix Hybrid MMF implants and surgical instruments for sterilization, storage and handling. The OsteoMed QuickFix Hybrid MMF Sterilization Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The tray is not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDAcleared sterilization wrap in order to maintain sterility of the enclosed devices. The sterilization trays may also be used in conjunction with a legally marketed rigid container. Sterilization validation was done for the OsteoMed QuickFix Hybrid MMF device and accessories. Do not exceed a maximum load of 2.3 lbs. in the sterilization tray. Validated sterilization parameters for OsteoMed QuickFix Hybrid MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Temperature: 270°F (132°C)	Similar

	ExtremiFix Mini & Small System Tray in a wrapped configuration: Method: Steam Cycle Pre-Vacuum Temperature: 270°F (132°C) Exposure Time: 4 minutes Minimum Dry Time: 50 minutes Validated sterilization parameters for OsteoMed ExtremiFix Mini & Small System Tray in a rigid container configuration: Method: Steam Cycle Pre-Vacuum Temperature: 270°F (132°C) Minimum Dry Time: 30 minutes	Exposure Time: 4 minutes Minimum Dry Time: 30 minutes	

SUMMARY OF NON-CLINICAL TESTING

The testing provided below was performed to demonstrate whether the subject device met the performance acceptance criteria of the respective standard listed below:

Biocompatibility Testing

A biocompatibility evaluation was conducted according to FDA guidance document "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, dated June 16, 2016. The subject device does not have direct contact with patients. The implants and instruments to be sterilized in the subject device will have contact with the subject device's surfaces; therefore, the subject device's case, trays, and modules have indirect contact with the patient. The subject device indirect patient contact materials are similar materials that were previous cleared with the predicate device, K173391, and the reference device, K143579.

The subject device met testing requirements for:

- Cytotoxicity
- Sensitization
- Irritation
- Pyrogen testing

Bench Testing

The following table provides a summary of the bench testing conducted.

Test Description	Purpose	Acceptance Criteria	Summary of Test Results
Design Validation	To validate the design and performance of the ExtremiFix Mini & Small System.	Surgeons evaluated the functionality of the tray.	Pass; met all requirements

Test Description	Purpose	Acceptance Criteria	Summary of Test Results
Ship Testing	To establish that the ExtremiFix Mini & Small System, and associated packaging, protects and retains the implants and instruments during normal shipping and handling.	Ship packaged plate per ASTM D-4169 and evaluate package contents for damage upon return.	Pass
Cleaning Validation (reusable instruments)	To validate the prescribed manual cleaning process for the ExtremiFix Mini & Small System.	Use the T7 cannulated long driver as worst-case device to verify that re-useable instruments can be cleaned per instructions to achieve standard requirements for reusable devices per AAMI TIR 12 and AAMI TIR 30.	Pass
Sterilization Validation	To validate the steam sterilization parameters for the ExtremiFix Mini & Small System to ensure that the fully-populated system can be sterilized.	Validate sterilization parameters with 3 consecutive tests. Conducted test for both systems wrapped in polypropylene sterile wrap and system enclosed in rigid container.	Passed for both sterile wrap and rigid container configurations
Reliability Verification (Sterilization Cycles Validation)	To assess the reliability, via repeated use and sterilization, of the ExtremiFix Mini & Small System.	Verify functionality and graphics legibility after the system tray is steam sterilized for 100 cycles with the sterilization parameters described in the IFU.	Passed functional and visual criteria after 100 cycles
Cytotoxicity	The Minimal Essential Media (MEM) Elution test was designed to determine the cytotoxicity of extractable substances.	The ANSI/AAMI/ISO 10993-5 standard states that the achievement of a numerical grade	Pass

		greater than 2 is considered cytotoxic effect, or a failing score.	
Sensitization	To determine the potential sensitization effects of subject device indirect contact materials.	The test is considered negative for signs of sensitization if the positive response observed is in less than 10% of the test animals.	Pass
Irritation	To determine the potential irritation effects of subject device indirect contact materials.	The requirements of the test will be met if the difference between the test article mean score and control mean score is 1.0 or less.	Pass
Pyrogen testing	The Bacterial Endotoxins Test, or Limulus Amebocyte Lysate (LAL) test, is an in vitro assay to detect and quantify bacterial endotoxin, a component of the cell wall of Gram negative bacteria.	For medical devices, the endotoxin limit is not more than 20.0 EU/device.	Pass

The results on the non-clinical testing demonstrated that the subject device met the acceptance criteria of the standard.

Animal Study

No animal studies were performed to demonstrate safety and efficacy.

Clinical Studies

No clinical studies were performed to demonstrate safety and efficacy.

VII. CONCLUSIONS

The conclusions drawn from the nonclinical tests demonstrate that the OsteoMed ExtremiFix Mini & Small System Tray is as safe, as effective, and performs as well as or better than the legally marketed device OsteoMed MMF Sterilization Tray (K173391) under regulation 21 CFR 880.6850, product code KCT.