May 10, 2018

OsteoMed, LLC
Kathryn Jayne
Manager, Regulatory Affairs
3885 Arapaho Rd.
Addison, TX 75001

Re: K173391
Trade/Device Name: OsteoMed MMF Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Tray
Regulatory Class: Class II
Product Code: KCT
Dated: April 09, 2018
Received: April 10, 2018

Dear 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 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.htmfor 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,

Geeta K.
Pamidimukkala -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

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)*
K173391

Device Name
OsteoMed MMF Sterilization Tray

Indications for Use *(Describe)*
The OsteoMed MMF Sterilization Tray is intended to contain MMF implants and surgical instruments for sterilization, storage and handling. The OsteoMed MMF Sterilization Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The 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 sterilization tray may also be used in conjunction with a legally marketed rigid container.

Sterilization validation was performed on MMF implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 2.3 lbs. in the sterilization tray.

Validated sterilization parameters for OsteoMed MMF Sterilization Tray:
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.

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

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"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-K173391

I. SUBMITTER

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Date Prepared: May 08, 2018

II. DEVICE

Name of the Device:	***OsteoMed MMF Sterilization Tray***
Common or Usual Name:	Sterilization Tray
Classification Name:	Sterilization Wrap Containers, Trays, Cassettes & Other Accessories
Regulation:	21 CFR 880.6850
Regulatory Class:	II
Product Code:	KCT

III. PREDICATE DEVICE

Primary Predicate: NuVasive® Sterilization Trays (K143579)

IV. DEVICE DESCRIPTION

The OsteoMed MMF Sterilization Tray is composed from a material commonly used (anodized and non-anodized Aluminum) to enclose, protect, and organize

OsteoMed's dental non-sterile devices, which meet national or international standards. The OsteoMed MMF Sterilization Tray is intended to provide storage for appropriate dental (MMF) devices and accessories during sterilization, storage, and transportation within the hospital environment.

The tray is composed of a base, a lid, and locking latch that secure the device and accessories. The tray is 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 MMF Sterilization Tray is designed to be used with standard autoclaves used in hospitals and healthcare facilities. As such, the OsteoMed MMF Sterilization Tray is effective for containing devices during sterilization and have been designed to withstand repeated steam sterilization cycles.

V. INDICATIONS FOR USE

The OsteoMed MMF Sterilization Tray is intended to contain MMF implants and surgical instruments for sterilization, storage and handling. The OsteoMed MMF Sterilization Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The 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 sterilization tray may also be used in conjunction with a legally marketed rigid container.

Do not exceed a maximum load of 2.3 lbs. in the sterilization tray.

Validated sterilization parameters for OsteoMed MMF Sterilization Tray:

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

At a high level, the subject and predicate devices are substantially equivalent based on the following same technological elements as demonstrated below.

Characteristics	OsteoMed MMF Sterilization Tray Subject Device	NuVasive Sterilization Trays Predicate Device (K143579)	Comparison
Product Code	KCT	KCT	Same

21 CFR	880.6850	880.6850	Same
System Components	Base, lid, locking latch	Base, lid, insert trays, brackets, caddies	Similar
Material Composition	Aluminum	Aluminum, Nylon, Silicone, Stainless Steel, Polypropylene, Polyphenylsulfone	Similar
Physical Properties	Evenly distributed perforated hole	Evenly distributed perforated hole	Same
Configurations/ Dimensions (L x W x H) in.	Rectangle base with lid (9.5 x 5.0 x 1.5)	Rectangle base with lid, inserts, brackets and caddies; Multiple dimensions to accommodate different product configurations (9.8 x 6.3 x 3.6)	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	30 minutes	Same
Vent to Volume Ratio	0.050 in^2/in^3	unknown	unknown
Reusable	Yes	Yes	Same

Characteristics	OsteoMed QuickFix Hybrid MMF Sterilization Tray	NuVasive Sterilization Trays	Comparison
Indications of Use	The OsteoMed MMF Sterilization Tray is intended to contain MMF implants and surgical instruments for sterilization, storage and handling. The OsteoMed MMF Sterilization Tray is suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The 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 sterilization tray may also be used in conjunction with a legally marketed rigid container. Sterilization validation was performed on MMF implants and accessories such as surgical instrumentation. Do not exceed a maximum load of 2.3 lbs. in the sterilization tray. Validated sterilization parameters for OsteoMed MMF Sterilization Tray: Method: Steam Cycle Pre-Vacuum Temperature: 270°F (132°C) Exposure Time: 4 minutes Minimum Dry Time: 30 minutes	The NuVasive Sterilization Trays are intended to contain NuVasive implants and surgical instruments for sterilization, storage and handling. The NuVasive Sterilization Trays are suitable for dynamic air removal (pre-vacuum) steam sterilization methods. The trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap in order to maintain sterility of the enclosed devices. Sterilization validations for three level worst case tray (20.5" x 10" x 7.375") included three different loading configurations: implant only content (26.4 lbs.), instrument only content (39.95 lbs.) and mixed instruments and implants content (30.45 lbs.) Validated worst case loading configurations included 23 instruments with lumens including the following worst case lumen dimensions: - 1.6 mm x 306.8 mm - 1.1 mm x 166.4 mm - 7.2 mm x 331.9 mm - 5.5 mm x 356.9 mm Do not exceed a maximum load of 25 lbs in the sterilization tray. Validated sterilization parameters for NuVasive Sterilization Trays: Method: Steam Cycle: Pre-Vacuum Temperature: 270°F (132°C) Exposure Time: 4 minutes Minimum Dry Time: 30 minutes Minimum Cool Down Time: 40 minutes	Similar

VII. PERFORMANCE DATA

Bench Testing

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

Test Description	Test Method Description	Summary of Test Results
Design Validation	Surgeons evaluated the functionality of the tray.	Pass; met all requirements
Ship Testing	Ship packaged plate per ASTM D-4169 and evaluate package contents for damage upon return	Pass
Cleaning Validation (reusable instruments)	Use the ratchet handle 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 30.	Pass
Sterilization Validation	Validate sterilization parameters with 3 consecutive tests. Conduct test for both system wrapped in polypropylene sterile wrap and system enclosed in rigid container.	Passed for both sterile wrap and rigid container configurations
Sterilization Cycles Validation	The device was steam sterilized for 100 cycles with the sterilization parameters described in the IFU The subject device was then evaluated to determine if it met pre-determined acceptance criteria.	Passed functional and visual criteria after 100 cycles

Bench testing was conducted on production equivalent devices. The devices passed the pre-acceptance criteria.

A tolerance study was conducted for the lid and latch of the sterilization tray.

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

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, subject Instrument trays, are substantially equivalent to, and are as safe and as effective as, the legally marketed predicate device, NuVasive® Sterilization Trays cleared under K143579 under regulation 21 CFR 880.6850, product code KCT.