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

March 31, 2016

ConMed Corporation
Ms. Dionne Sanders, MS, CQA, RAC
Manager, Regulatory Affairs
11311 Concept Blvd.
Largo, Florida 33773

Re: K152969
Trade/Device Name: Enhance Allograft Wedge Instrument Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: March 02, 2016
Received: March 03, 2016

Dear Ms. Sanders:

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" (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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
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Office of Device Evaluation
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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)*
K152969

Device Name
Enhance Allograft Wedge Instrument Tray

Indications for Use *(Describe)*

The Enhance Allograft Wedge Instrumentation Tray (T903) is a containment device intended for medical device sterilization. The Enhance Allograft Wedge Instrumentation Tray is used for loading surgical instruments in order to conveniently organize, sterilize, transport, and store the instruments between uses. This tray is intended for use with the following instruments:

REF	Description	REF	Description
903106	Evans Trial 6mm	903206	Cotton Trial 6mm
903108	Evans Trial 8mm	903207	Cotton Trial 7mm
903110	Evans Trial 10mm	903208	Cotton Trial 8mm
903112	Evans Trial 12mm	903006	Mallet
903010	Tamp Evans	903008	Distractor
903012	Tamp Cotton	903002	Osteotome 16mm
903205	Cotton Trial 5mm	903004	Osteotome 10mm

The Enhance Allograft Wedge Instrumentation Tray (T903) 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 medical instruments. Sterilize the instrument tray using the following sterilization parameters:

Method	Cycle	Temperature	Exposure	Dry Cycle	Cool Down	Duration
Steam (wrapped)	Pre-vacuum	270°F (132°C)	4 minutes	20 minutes	118°F (48°C)	25 minutes
Steam (wrapped)	Gravity	250°F (121°C)	30 minutes	15 minutes	118°F (48°C)	37 minutes

- Validation was conducted using an FDA cleared sterilization wrap with a maximum load 14 lbs.(6.4 kg).
- Only single unstacked trays may be used during the sterilization process.
- Double wrap tray using an FDA cleared wrap.

☐ 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.

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

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510(k) SUMMARY

I. SUBMITTER

CONMED Corporation
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Largo, Florida 33773

Phone: 727-399-5564
Fax: 727-399-5264

Contact Person: Dionne Sanders, RAC
Date Prepared: March 25, 2016
510k#: K152969

II. DEVICE

Name of Device:	Enhance Allograft Wedge Instrument Tray
Common Name:	Sterilization Tray
Classification Name:	Sterilization Wrap (21 CFR Part 880.6850)
Regulatory Class:	Class II
Product Codes:	KCT

III. PREDICATE DEVICE

Device Name:	ConMed Linvatec Anodized Aluminum Sterilization Trays
Company Name:	ConMed Linvatec
510(k) #:	K090560

IV. DEVICE DESCRIPTION

The Enhance® Allograft Wedge Instrumentation Tray (T903) is constructed primarily of aluminum with perforations to facilitate sterilant penetration, evacuation and drying. The tray dimensions are approximately 21 x 10” and it is designed to fit any standard autoclave. The tray is manufactured from durable, biocompatible materials that are corrosion resistant and compatible with the environment of repeated steam sterilization. Since the tray is perforated, an FDA cleared sterilization wrap must be used to maintain sterility of the contents. Although the tray is reusable it will not be serviced or repaired. Interior structures of the trays have the ability to separately hold individual instruments during the entire duration they are in contact with the tray.

V. INTENDED USE / INDICATIONS FOR USE

The Enhance Allograft Wedge Instrumentation Tray (T903) is a containment device intended for medical device sterilization. The Enhance Allograft Wedge

Instrumentation Tray is used for loading surgical instruments in order to conveniently organize, sterilize, transport, and store the instruments between uses.

This tray is intended for use with the following instruments:

REF	Description	REF	Description
903106	Evans Trial 6mm	903206	Cotton Trial 6mm
903108	Evans Trial 8mm	903207	Cotton Trial 7mm
903110	Evans Trial 10mm	903208	Cotton Trial 8mm
903112	Evans Trial 12mm	903006	Mallet
903010	Tamp Evans	903008	Distractor
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903205	Cotton Trial 5mm	903004	Osteotome 10mm

The Enhance Allograft Wedge Instrumentation Tray (T903) 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 medical instruments. Sterilize the instrument tray using the following sterilization parameters:

Method	**Cycle**	**Temperature**	**Exposure**	**Dry Cycle**	**Cool Down**	**Duration**
Steam (wrapped)	Pre-vacuum	270°F (132°C)	4 minutes	20 minutes	118°F (48°C)	25 minutes
Steam (wrapped)	Gravity	250°F (121°C)	30 minutes	15 minutes	118°F (48°C)	37 minutes

- Validation was conducted using an FDA cleared sterilization wrap with a maximum load 14 lbs. (6.4 kg).
- Only single unstacked trays may be used during the sterilization process.
- Double wrap tray using an FDA cleared wrap.

VI. COMPARISION OF THE TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

ConMed's Enhance Allograft Wedge Instrument Tray is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the ConMed Linvatec Anodized Aluminum Sterilization Trays, specifically the Hip Arthroscopy Master Tray, and raises no new issues of safety or effectiveness.

The similarities and differences between the predicate and proposed sterilization trays are the following-

	Proposed Device Enhance Allograft Wedge Instrument Tray	**Predicate Device** ConMed Linvatec Anodized Aluminum Sterilization Tray (K090560)
Intended Use	Same	A family of containment devices for medical device sterilization.
Indications for Use	Same	The trays are intended for use only with the instruments sets listed in the IFU.
Contraindications	None Known	None known
Materials of Construction	Tray lid, base and internal tray: 5052-H32 grade aluminum, anodized Rivets, Handle Wire, Handle Clip, Latch Component, Channel: 301SS, 302SS, 304SS, Silicone Latches, Screws, Nuts, Washers and Brackets: 17-4 PH SS, 304-2B SS, 316SS, 18-8 SS Brackets, Internal: Silicone Silk Screen Ink: Sericoil 301 TP Black	Tray lid, base and internal tray: 5052-H32 grade aluminum, anodized Handles: 304SS Latches: 304SS Brackets and protective mat: Silicone (21 CFR177.2600)
Design	Same	Perforated tray and lid used to organize, sterilize, transport, and store instruments between uses
Overall Dimensions	21.29” x 10.03” x 3.30”	20.77” x 10.02” x 6.00”
Filled Weight	11.70lbs	18.20lbs
Gaskets, Filters, Valves, Seals	Same	None
Latches	Same	Yes, to secure the tray lid to the base
Sterilization Method	Same	Steam sterilization using a FDA-cleared sterilization wrap
External Stacking	Same	Do not stack
Pre-vacuum cycle Steam (wrapped)	Same w/added cool down time Cool down: 48° C for 25 minutes	Min temperature: 270° F (132° C) Min exposure: 4 min Min dry cycle: 20 min
Gravity cycle Steam (wrapped)	Method: Steam (wrapped) Temperature: 250° F (121° C) Exposure: 30 min Dry Cycle: 15 min Cool Down: 48° C for 37 min	Method: Steam (wrapped) Min temperature: 270° F (132° C) Min exposure: 15 min Min dry cycle: 25 min
Sterility Assurance Level (SAL)	SAL 10^{-6}	SAL 10^{-6}
Tamper Evident	Same	Secured with autoclave tape
Instrumentation	Same	For use with specific instrumentation
Packaging	Shipped empty	Shipped loaded with instrumentation

VII. PERFORMANCE DATA

Non-Clinical Performance

ConMed conducted verification and validation testing including performance testing in accordance with ANSI/AAMI ST77:2013 Containment Devices for Reusable Medical Device Sterilization as well as: handle strength verification, cleaning, biocompatibility, packaging and transportation and a non-clinical user validation. Based on this testing, it has been determined that the subject device is as safe, as effective and performs at least as safely and effectively as the legally marketed predicate device cleared under (K090560).

Clinical Performance

This submission does not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

VIII. CONCLUSION

The Enhance Allograft Wedge Instrument Tray is substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the predicate device.

IX. SUBSTANTIAL EQUIVALENCE STATEMENT

The performance testing data for the subject device Enhance Allograft Wedge Instrument Tray (T903) demonstrates the subject device is as safe, as effective, and performs as well as the predicate device (K090560).