



Food and Drug Administration
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January 25, 2016

Ellipse Technologies, Incorporated
Ms. Cora Sim
Regulatory Affairs Specialist
101 Enterprise, Suite 100
Aliso Viejo, CA 92656

Re: K151594

Trade/Device Name: Ellipse Supplemental Instrument Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: II
Product Code: KCT
Dated: December 28, 2015
Received: December 29, 2015

Dear Ms. Sim:

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 and Part 809); 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 and Part 809), 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,

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

Erin Keith, M.S.
Director
Division of Anesthesiology,
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Infection Control, and Dental Devices
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Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K151594

Device Name
Ellipse Supplemental Instrument Trays

Indications for Use (Describe)

The Ellipse Supplemental Instrument Trays are intended to organize, protect, and transport instruments during steam sterilization and subsequent storage. Sterility of the enclosed instruments is not maintained unless used in conjunction with an FDA-cleared sterilization wrap using the following cycle:

Pre-vacuum Steam Sterilization parameters: 132°C for 4 minutes with 40 minutes dry time

The the worst case validated sterilization load is:

-One (1) Supplemental Instrument Tray with instruments (total weight: 10.0 lbs.) and one (1) Supplemental Reamer Tray with instruments (total weight: 13.1 lbs.); in a non-stacked configuration.

The worst case loading configuration included the 12 instruments supplied with the Supplemental Instrument Tray with the following worst case lumen dimensions:

Supplemental Instrument Tray (Model SIT1-000)

Instrument Model	Description	Dimension (Inner Diameter x Length)	Number of Lumens
TCD1-000	Teardrop Cannulated Driver	0.210" x 4.58"	1
CED1-011	11mm Cannulated Entry Drill	0.146" x 10.75"	1
GWC1-000	Guide Wire Chuck	0.250" x 5.0"	1
LQC1-000	Large AO Quick Connect	0.175" x 2.91"	1
DGA1-000	Direct AO Depth Gauge	0.394" x 10.43"	1

The worst case loading configuration included the 18 instruments supplied with the Supplemental Reamer Tray with the following worst case lumen dimensions:

Supplemental Reamer Tray (Model SRT1-000):

Instrument Model	Description	Dimension (Inner Diameter x Length)	Number of Lumens
RMR1-110	Flexible Reamer, 10.0mm	0.125" x 18.4"	1
RMR1-135	Flexible Reamer, 13.5mm	0.125" x 18.4"	1
RMR1-140	Flexible Reamer, 14.0mm	0.125" x 18.4"	1
RMR1-145	Flexible Reamer, 14.5mm	0.125" x 18.4"	1
RMR1-150	Flexible Reamer, 15.0mm	0.125" x 18.4"	1

Do not exceed a maximum load of 12 instruments (10.0 lbs.) in the Supplemental Instrument Tray.

Do not exceed a maximum load of 18 instruments (13.1 lbs.) in the Supplemental Reamer Tray.

List of Devices:

Model	Dimensions (Length x Width x Depth)	Number of Instruments:	Validated Weight of tray with instruments:
SIT1-000	510mm x 250mm x 45mm	12	10.0 lbs.
SRT1-000	510mm x 250mm x 87mm	18	13.1 lbs.*

*Includes insert tray with dimensions 497mm x 240mm x 52mm

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.

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510(k) Summary (pursuant to 21 CFR 807.92 (a)(1))

**Ellipse Supplemental Instrument Trays
Premarket Notification Number: K151594
January 22, 2016**

- 1. Company:** Ellipse Technologies, Incorporated
101 Enterprise, Suite 100
Aliso Viejo, CA 92656
USA

Contact: Cora Sim
Regulatory Affairs Specialist
Phone: (949) 837-3600 ext. 221
Fax: (949) 837-3664
- 2. Proprietary Trade Name:** Ellipse Supplemental Instrument Trays
- 3. Classification Name:** Sterilization Wrap Containers, Trays, Cassettes & Other Accessories (21 CFR 880.6850)
- 4. Product Code:** KCT (Sterilization wrap)
- 5. Device Classification:** Class II
- 6. Predicate Device:** The Ellipse Supplemental Instrument Trays are substantially equivalent to the following 510(k) cleared device:

 - ContainMed, Inc. VersaPod™ Instrument Trays (K071783)
- 7. Product Description:** The Ellipse Supplemental Instrument Trays are comprised of a Supplemental Instrument Tray and a Supplemental Reamer Tray. These trays are designed to organize, protect, and transport instruments during steam sterilization and subsequent storage. The trays are composed of a lid and base tray with handles and are perforated for steam penetration. The Supplemental Instrument Tray has the following approximate external dimensions: 510 mm (length) x 250 mm (width) x 45 mm (depth), and is designed to hold 12 instruments. The Supplemental Reamer Tray has the following external dimensions: 510 mm (length) x 250 mm (width) x 87 mm (depth), and is designed to hold 18 flexible reamer

instruments. An insert tray with the following dimensions is used with the Supplemental Reamer Tray: 497 mm (length) x 240 mm (width) x 52 mm (depth). The Supplemental Instrument Trays are reusable and are used to store instruments prior to, during, and after the sterilization process. The trays are made of anodized aluminum and have medical grade, Class VI Silicone instrument holders with stainless steel mounting hardware which are used to secure, separate, and organize the instruments within the trays. The tray handles are also encased in medical grade, Class VI Silicone.

8. Indications for Use: The Ellipse Supplemental Instrument Trays are intended to organize, protect, and transport instruments during steam sterilization and subsequent storage. Sterility of the enclosed instruments is not maintained unless used in conjunction with an FDA-cleared sterilization wrap using the following cycle:

Pre-vacuum Steam Sterilization parameters: 132°C for 4 minutes with 40 minutes dry time

The worst case validated sterilization load is:

- One (1) Supplemental Instrument Tray (total weight: 10.0 lbs.) and one (1) Supplemental Reamer Tray (total weight: 13.1 lbs.); in a non-stacked configuration

The worst case loading configuration included the 12 instruments supplied with the Supplemental Instrument Tray with the following worst case lumen dimensions:

Supplemental Instrument Tray (Model SIT1-000)

Instrument Model	Description	Dimensions (Inner Diameter x Length)	Number of Lumens
TCD1-000	Teardrop Cannulated Driver	0.210" x 4.58"	1
CED1-011	11mm Cannulated Entry Drill	0.146" x 10.75"	1
GWC1-000	Guide Wire Chuck	0.250" x 5.0"	1
LQC1-000	Large AO Quick Connect	0.175" x 2.91"	1
DGA1-000	Direct AO Depth Gauge	0.394" x 10.43"	1

The worst case loading configurations included the 18 instruments supplied with the Supplemental Reamer Tray with the following worst case lumen dimensions:

Supplemental Reamer Tray (Model SRT1-000):

Instrument Model	Description	Dimensions (Inner Diameter x Length)	Number of Lumens
RMR1-110	Flexible Reamer, 10.0mm	0.125" x 18.4"	1
RMR1-135	Flexible Reamer, 13.5mm	0.125" x 18.4"	1
RMR1-140	Flexible Reamer, 14.0mm	0.125" x 18.4"	1
RMR1-145	Flexible Reamer, 14.5mm	0.125" x 18.4"	1
RMR1-150	Flexible Reamer, 15.0mm	0.125" x 18.4"	1

Do not exceed a maximum load of 12 instruments (10.0 lbs.) in the Supplemental Instrument Tray.

Do not exceed a maximum load of 18 instruments (13.1 lbs.) in the Supplemental Reamer Tray.

List of Devices:

Model	Dimensions (Length x Width x Depth)	Number of Instruments	Validated Weight of tray with instruments
SIT1-000	510mm x 250mm x 45mm	12	10.0 lbs.
SRT1-000	510mm x 250mm x 87mm	18	13.1 lbs.*

*Includes insert tray with dimensions 497mm x 240mm x 52mm.

9. Technological Characteristics: Substantial equivalence of the Ellipse Supplemental Instrument Trays to the predicate is based on similar intended use, design, principles of operation, and materials of composition. The Ellipse Supplemental Instrument Trays and the predicate device have a similar intended use, the same design, and the same principles of operation. Specifically, the Ellipse Supplemental Instrument Trays and the predicate device are both intended to organize, protect, and transport instruments during steam sterilization and subsequent storage. The Ellipse Supplemental Instrument Trays have the same design features as that of the predicate. Both the Ellipse Supplemental Instrument Trays and the predicate are reusable, rigid

sterilization containers. Both the Ellipse Supplemental Instrument Trays and predicate device have similar dimensions and are made of the same materials.

Device Comparison Table for Substantial Equivalence:

Manufacturer	Predicate ContainMed	Ellipse Technologies, Inc.
510(k) Number	K071783	K151594
Product Code	KCT	KCT
Intended Use	Perforated instrument trays to organize, protect, and transport medical instruments during pre-vacuum steam sterilization and subsequent storage.	The Ellipse Supplemental Instrument trays are designed to store various reusable instruments in order to organize, protect, and transport instruments during steam sterilization and subsequent storage.
Design	Anodized aluminum tray with securing lid and base tray with handles. An optional anodized aluminum insert tray is available for use with the 82mm deep base only. Anodized aluminum placard, and silicone rubber mat and instrument holding accessories (with stainless steel mounting hardware), are available to identify, organize, and protect the contents during use.	The lid, base tray, and insert tray are composed of anodized aluminum. An internal individual insert tray is utilized by the Supplemental Reamer Tray. Medical grade Class VI Silicone instrument holders and with stainless steel mounting hardware are used to secure, separate, and organize the instruments within the trays.
Dimensions	Base tray: 510mm (length) x 250mm (width) x 40mm, 60mm, or 82mm (depth)	Supplemental Instrument Tray: Base tray: 510mm (length) x 250mm (width) x 45mm (depth) Supplemental Reamer Tray: Base tray: 510mm (length) x 250mm (width) x 87mm (depth) Insert Tray: 497 mm (length) x 240 mm (width) x 52 mm (depth).*
Material composition	Anodized aluminum, Stainless Steel, Silicone	Anodized aluminum, Stainless Steel, Silicone
Physical Properties	Evenly distributed perforated hole pattern.	Evenly distributed perforated hole pattern.
Sterilization Method	Steam	Steam
Sterilant Penetration	Sterilant (steam) penetration through perforations in tray	Sterilant (steam) penetration through perforations in tray.
Sterilization cycle	Pre-vacuum	Pre-vacuum
Exposure Temperature	132° C	132° C
Exposure time	4 minutes	4 minutes

Dry Time	45 minutes	40 minutes
Air permeance	Yes	Yes
Diameter of each perforation	0.197 inches	0.197 inches
Number of perforations	Tray Lid: 916 Base Tray: 1,044 Insert Tray: 1,044	The Supplemental Instrument Tray: Tray Lid: 916 Base Tray: 871 The Supplemental Reamer Tray: Tray Lid: 916 Base Tray: 956 Insert Tray: 948
Vent to volume ratios	0.045 in ⁻¹	Supplemental Instrument Tray: 0.192 in ⁻¹ Supplemental Reamer Tray: 0.147 in ⁻¹
Material compatibility with sterilization process	Materials of construction are compatible with steam sterilization.	The materials used in the Ellipse Supplemental Instrument Trays were exposed to 100 sterilization cycles and no material degradation was observed. All materials maintained their integrity and remained fully functional. Performance testing demonstrated that the materials of construction are compatible with steam sterilization.
Toxicological properties	Materials of construction are biocompatible.	Extracts of test article (polymeric component) on L-939 mouse fibroblast cells in MEM elution assay did not display a cytotoxic response and is considered non-cytotoxic. Testing demonstrated that the materials of construction are biocompatible.
Results of transportation studies	Not available.	Shipping validation was performed on the Ellipse Supplemental Instrument Trays. The package performance testing results demonstrated all acceptance criteria were met.
Summary of cleaning validation information	Manual cleaning with use of neutral pH (pH 6.0-8.0) enzymatic detergent recommended.	The Ellipse Supplemental Instrument Trays have been validated to be cleaned using both a manual and automated process. Hemoglobin, Micro BCA protein, and TOC test results met all acceptance criteria.

<p>Limitations of reprocessing</p>	<p>The materials used in the ContainMed VersaPod™ Instrument Trays may be sterilized for an indefinite number of cycles. The life of the system is limited only by irreparable physical damage from mishandling.</p>	<p>The function and physical construction of the Supplemental Instrument Trays and their components are safe and effective after exposure to 100 sterilization cycles. The end of tray life is determined through the inspection of each tray after the required cleaning and sterilization cycles. The life of the trays are limited only by irreparable physical damage from mishandling.</p>
<p>Summary of drying time validation</p>	<p>Dry time of 45 minutes was validated for use in the pre-vacuum steam cycle of 132°C for 4 minutes.</p>	<p>The dry time validation was successful in determining an effective dry time of 40 minutes for the validated pre-vacuum steam sterilization cycle. Acceptance criteria below were met during validation of the dry time:</p> <ol style="list-style-type: none"> 1) Autoclave data showing appropriate dwell time at 132°C (+3°C) for each full cycle 2) Confirmation of the absence of moisture on the trays and sterilization wrap 3) No more than 3% difference in weight prior to and after sterilization

*For use with the Supplemental Reamer Tray

10. Performance Testing: Non-clinical performance testing was conducted to establish substantial equivalence of the Ellipse Supplemental Instrument Trays to the predicate device. Sterilization validation testing was conducted to confirm that a sterility assurance level (SAL) of 10⁻⁶ was achieved at the validated sterilization parameter in the pre-vacuum steam sterilization cycle according to ISO 17665-1 and AAMI TIR 12. Dry time validation was performed following full cycles. Performance testing was conducted to demonstrate that the function and physical construction of the Ellipse Supplemental Instrument Trays and its components are maintained after exposure to 100 sterilization cycles.

11. Conclusion: Based on the indications for use, technological characteristics, non-clinical performance data, and a comparison to the predicate device, the Ellipse Supplemental Instrument Trays have been shown to be substantially equivalent to the legally marketed predicate device.