DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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May 12, 2016

Microline Surgical, Inc.
Anu Gaur, Ph.D., MBA, MSRA, RAC
Regulatory Affairs Manager
50 Dunham Road, Suite 1500
Beverly, MA 01915

Re: K152745
Trade/Device Name: ReNew Sterilization Trays [Catalog #3708 and #3709]
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 01, 2016
Received: April 04, 2016

Dear Dr. Anu Gaur:

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
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental 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)*
K152745

Device Name
ReNew Sterilization Trays (Catalog #3708 and #3709)

Indications for Use *(Describe)*
Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are intended to protect the ReNew Reusable Tips (Scissors, Graspers and Dissectors) and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with 2 layers of FDA-cleared 1-ply polypropylene sterilization wrap, sterility of the enclosed sterilization trays (Catalog #3708 and #3709) is maintained until used.

The Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are used to secure the ReNew Reusable Tips (Scissors, Graspers and Dissectors). Catalog #3708 measures at 7.8" length , 4.31" width, and 1.22" height , in dimensional measurements, as intended load during the transport, sterilization and storage between their intended use. Similarly, Catalog #3709 measures at 6.32" length, 3.32" width, and 1.21" height, in dimensional measurements as intended load during the transport, sterilization and storage between their intended use.

The ReNew Sterilization Tray (Catalog #3708 & 3709) have been validated with the ReNew Reusable Tips (Scissors,Graspers and Dissectors) wrapped in 2 layers of FDA-cleared 1-ply polypropylene wrap weighing a calculated total weight of 280.52 grams, for Catalog number 3708, and 148.195 grams for Catalog #3709. The validation included Cleaning Validation (Automated and Manual) Testing and Steam Sterilization Cycles. The validated prevacuum cycle parameters are as follows: time: 4 minutes at temperature 132 °C, with a dry time of 30 minutes. The validated gravity cycle parameters are as follows: Time: 30 minutes at 121 °C with a dry time of 20 minutes, as well as time: 15 minutes at temperature 132 °C with a dry time of 20 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.

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Traditional 510(k) Summary
[As Required by 21 CFR § 807.92]

510(k) Submitter:	Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA
Establishment Registration Number:	1223422
Contact Representative:	Anu Gaur, Ph.D., MBA, MSRA, RAC Regulatory Affairs Manager Phone: 978-867-1726 Fax: 978-922-9209
Date Prepared:	May 12, 2016
Trade Name:	ReNew Sterilization Trays [Catalog #3708 and #3709]
Common Name(s):	Sterilization Tray
Classification:	Class II, in accordance to 21 CFR § 880.6850 Sterilization Wrap.
Classification Product Code(s):	KCT
Regulation Medical Specialty:	General Hospital
Predicate Device(s):	PolyVac Surgical Instrument Delivery System (K012105)

Device Description:

Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) intended purpose is to secure the ReNew Tips (Graspers, Dissectors, and Scissors) devices during its transportation, sterilization, and storage purposes.

Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) consist of a base, a lid and device holding brackets. The lid can be fastened to the base by means of a locking tab, which is designed as a part of the lid. The brackets are constructed from biomedical grade silicone material. These brackets are used to secure the intended devices during their transport, sterilization and storage purpose. The ReNew Sterilization Trays (Catalog #3708 and #3709) are intended to be used for ReNew Tips sterilization purpose which are non-porous devices including graspers, dissectors, and scissors.

ReNew Sterilization Tray (Catalog #3708)

The subject device ReNew Sterilization Tray (Catalog #3708) consists of a case, a cover and brackets. The Lid is 7.80" (Length) x 4.31" (Width) x 0.46" (Height) in dimensions; and the Base is 7.60" (Length) x 4.12" (Width) x 0.76" (Height).

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The ReNew Sterilization Tray (Catalog #3708) lid and base are designed using Radel® Polyphenylsulfone material, which can be reused with steam sterilization methods. The brackets are constructed from biomedical grade silicone material. To support steam sterilization, the ReNew Sterilization Tray and Lid have an evenly distributed hole pattern in relation to its size for penetration of steam during sterilization process.

ReNew Sterilization Tray (Catalog #3709)

The subject device ReNew Sterilization Tray (Catalog #3709) consists of a case, a cover and brackets. The Lid is 6.32" (Length) x 3.32" (Width) x 0.44" (Height) with ±0.02 in dimensions; and the Base is 6.15" (Length) x 3.14" (Width) x 0.77" (Height) with ±0.02 in dimensions. The ReNew Sterilization Tray (Catalog #3709) lid and base are designed using Radel® Polyphenylsulfone material, which can be reused with steam sterilization methods. The brackets are constructed from biomedical grade silicone material. To support steam sterilization, the ReNew Sterilization Tray and Lid have an evenly distributed hole pattern in relation to its size for penetration of steam during sterilization process.

Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are non-patient and non-blood/fluid contact devices during their intended use. Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are primarily packaged in a foam wrap (Polyethylene foam sheet) and a plastic Bag (Poly-bag) and Bubble wrap (Dura Bubble), and single wall, 32lbs/inch edge, crushed corrugated white cardboard shipping box, which does not need any special handling requirements during shipment.

Statement of Intended Use:

Indications for Use:

Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are intended to protect the ReNew Reusable Tips (Scissors, Graspers and Dissectors) and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with 2 layers of FDA-cleared 1-ply polypropylene sterilization wrap, sterility of the enclosed sterilization trays (Catalog #3708 and #3709) is maintained until used.

The Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are used to secure the ReNew Reusable Tips (Scissors, Graspers and Dissectors). Catalog #3708 measures at 7.8" length, 4.31" width, and 1.22" height, in dimensional measurements, as intended load during the transport, sterilization and storage between their intended use. Similarly, Catalog #3709 measures at 6.32" length, 3.32" width, and 1.21" height, in dimensional measurements as intended load during the transport, sterilization and storage between their intended use.

The ReNew Sterilization Tray (Catalog #3708 & 3709) have been validated with the ReNew Reusable Tips (Scissors, Graspers and Dissectors) wrapped in 2 layers of FDA-cleared 1-ply polypropylene wrap weighing a calculated total weight of 280.52 grams, for Catalog number 3708, and 148.195 grams for Catalog #3709. The validation included Cleaning Validation (Automated and Manual) Testing and Steam Sterilization Cycles. The validated prevacuum cycle parameters are as follows: time: 4 minutes at temperature 132 °C, with a dry time of 30 minutes. The validated gravity cycle parameters are as follows: Time: 30 minutes at 121 °C with a dry time of 20 minutes, as well as time: 15 minutes at temperature 132 °C with a dry time of 20 minutes.

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Comparison to Predicate Device:

Microline Surgical, Inc., has determined substantial equivalence of the subject devices ReNew Sterilization Trays (Catalog #3708 and #3709) with their legally marketed predicate device, PolyVac Surgical Instrument Delivery System (K012105); based on the principles of safety and effectiveness applicable to the 510(k) review including the applicable standard and the least burdensome approach.

Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are substantially equivalent to their predicate device, PolyVac Surgical Instrument Delivery System (K012105) including the following criteria;

- Selection of the applicable predicate device;
- Similarities in the intended use and indication for use;
- Similarities in materials for construction of device;
- Similarities in performance testing criteria;
- Similarities in the technological characteristics and fundamental technology.
- Does not raise new questions of safety and effectiveness; and
- Demonstrates at least as safe and effective as its legally marketed predicate device.

The differences between the predicate and the subject devices ReNew Applier Sterilization Trays (Catalog #3708 and #3709) are the following;

- Internal configuration of the ReNew Sterilization Tray (Catalog #3708) to secure and hold eighteen (18); and ReNew Sterilization Tray (Catalog #3709) to secure and hold nine (9) ReNew Tips (Graspers, Dissectors and Scissors) devices.

In summary, the subject devices ReNew Sterilization Trays (Catalog #3708 and #3709) are similar in design, materials, manufacturing, performance, safety, effectiveness, labeling, sterilization, and fundamental technological characteristics as applicable to their legally marketed predicate device, PolyVac Surgical Instrument Delivery System (K012105).

Summary of Technological Characteristics:

Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) intended purpose is to secure the ReNew Tips (18 and 9 configuration arrangements) device during its transportation, sterilization and storage purposes. The subject devices ReNew Sterilization Trays (Catalog #3708 and #3709) are technologically similar to their legally marketed predicate device, PolyVac Surgical Instrument Delivery System (K012105). The following pertains to the technological characteristics comparison presented in a tabular format.

ReNew Sterilization Tray (Catalog #3708)

Characteristics	Predicate Device	Subject Device (Proposed)
Trade Name	PolyVac Surgical Instrument Delivery System	Microline Surgical ReNew Sterilization Tray (Catalog #3708)
510(k) Number	(K012105)	This Submission
510(k) Clearance Date	Aug 02, 2002	Not Applicable
Classification	Class II 21 CFR § 880.6850	Class II 21 CFR § 880.6850
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & other Accessories.	Sterilization Wrap Containers, Trays, Cassettes & other Accessories.

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Classification Product Code	KCT	KCT
Common Name	Sterilization Wrap	Sterilization Tray
Regulation Medical Specialty	General Hospital	General Hospital
Environment of Use	Hospital, Operating Room (OR) Use (not specified).	Hospital, Operating Room (OR) Use only.
Intended Use (indications for Use)	PolyVac Delivery Systems are intended to protect medical device instrumentation and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used.	Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are intended to protect the ReNew Reusable Tips (Scissors, Graspers and Dissectors) and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with 2 layers of FDA-cleared 1-ply polypropylene sterilization wrap, sterility of the enclosed sterilization trays (Catalog #3708 and #3709) is maintained until used. The Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are used to secure the ReNew Reusable Tips (Scissors, Graspers and Dissectors). Catalog #3708 measures at 7.8" length, 4.31" width, and 1.22" height, in dimensional measurements, as intended load during the transport, sterilization and storage between their intended use. Similarly, Catalog #3709 measures at 6.32" length, 3.32" width, and 1.21" height, in dimensional measurements as intended load during the transport, sterilization and storage between their intended use. The ReNew Sterilization Tray (Catalog #3708 & 3709) have been validated with the ReNew Reusable Tips (Scissors, Graspers and Dissectors) wrapped in 2 layers of FDA-cleared 1-ply polypropylene wrap weighing a calculated total weight of 280.52 grams, for Catalog number 3708, and 148.195 grams for Catalog #3709. The validation included Cleaning Validation (Automated and Manual) Testing and Steam Sterilization Cycles. The

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		validated prevacuum cycle parameters are as follows: time: 4 minutes at temperature 132 °C, with a dry time of 30 minutes. The validated gravity cycle parameters are as follows: Time: 30 minutes at 121 °C with a dry time of 20 minutes, as well as time: 15 minutes at temperature 132 °C with a dry time of 20 minutes.
Technological Characteristics		
Primary Configuration	Plastic Tray	Plastic Tray
Primary Materials *(Construction)*	Polyphenylsulphone (Radel® R-5500) and Biomedical Grade Silicone.	Identical
Dimensions	**Lid:** 7.80" (Length) x 4.31" (Width) x 0.46" (Height) inches. **Base:** 7.60" (Length) x 4.12" (Width) x 0.76" (Height) inches.	Identical
Air Permeability	Yes	Yes
Intended for Reuse	Yes	Yes
Material Thickness	0.0625"	Identical
Hole Size	Ø 0.188"	Identical
Hole Pattern	**Lid:** Five (5)X in two (2) rows on bottom and top edges, Four (4)X – one (1) in each corner, Two(2)X – two(2) rows centrally aligned with bottom and top edge rows. **Base:** Five (5)X in Two (2) rows on bottom and top edges, Four (4)X – one (1) in each corner, Seven (7)X central row evenly spaced. [Centrally the lid includes the printed Company Logo and Trade Name].	Identical
Brackets	Two (2) rows - (.74) x (.29) with taper.	Identical
Feet	Four (4) on base, to align with the 4 holes in lid corners (0.1405" height)	Identical
Weight	270 grams	Identical
Sterilization Method(s)	Steam Sterilization & Ethylene Oxide (EtO)	Steam Sterilization only

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Sterilization Cycle Parameters	**Prevacuum Steam:** 132°C - 4 Mins Dry for 20 - 40 mins (as needed) **Gravity Air Displacement Cycle:** 132°C - 30 Mins **Gravity Steam:** 121°C - 55 Mins Dry for 20 - 50 mins (as needed)	**Prevacuum Steam:** 132°C – 4 minutes Dry for 30 minutes **Gravity Steam:** 121°C – 30 minutes Dry for 20 minutes **Gravity Steam:** 132°C –15 minutes Dry for 20 minutes
Sterility *(Disposable or Multiple Use)*	Multiple Use	Multiple Use
Patient Contact	No	No
Blood/Fluid Contact	No	No
Special Conditions *(Shipping and Handling)*	No	No
Manufacturer	**Contract Manufacturer:** Symmetry Medical, Inc. 253 Abby Road, Manchester, NH 03103 USA (Registration Number: 1221053) (Symmetry Medical OEM Solutions acquired by Tecomet, Inc., December 5, 2014)	Identical
Proposed Brand Labeling *(Relabeling, Repackaging and Market Distribution)*	Not Applicable	Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA
Differences in Technological Characteristics		
Tray Internal Configuration	Not Applicable	ReNew Sterilization Tray (Catalog #3708) internal configuration to secure the ReNew Tips (18 Tips configuration arrangement) only.

ReNew Sterilization Tray (Catalog #3709)

Characteristics	Predicate Device	Subject Device (Proposed)
Trade Name	PolyVac Surgical Instrument Delivery System	Microline Surgical ReNew Sterilization Tray (Catalog #3709)
510(k) Number	(K012105)	This Submission
510(k) Clearance Date	Aug 02, 2002	Not Applicable
Classification	Class II 21 CFR § 880.6850	Class II 21 CFR § 880.6850
Classification Name	Sterilization Wrap Containers, Trays, Cassettes & other Accessories.	Sterilization Wrap Containers, Trays, Cassettes & other Accessories.

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Classification Product Code	KCT	KCT
Common Name	Sterilization Wrap	Sterilization Tray
Regulation Medical Specialty	General Hospital	General Hospital
Environment of Use	Hospital, Operating Room (OR) Use (not specified).	Hospital, Operating Room (OR) Use only.
Intended Use (Indications for Use)	PolyVac Delivery Systems are intended to protect medical device instrumentation and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with an approved sterilization wrap, sterility of the enclosed medical device is maintained until used.	Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are intended to protect the ReNew Reusable Tips (Scissors, Graspers and Dissectors) and to facilitate the sterilization process by allowing steam penetration and air removal. When used in conjunction with 2 layers of FDA-cleared 1-ply polypropylene sterilization wrap, sterility of the enclosed sterilization trays (Catalog #3708 and #3709) is maintained until used. The Microline Surgical ReNew Sterilization Trays (Catalog #3708 and #3709) are used to secure the ReNew Reusable Tips (Scissors, Graspers and Dissectors). Catalog #3708 measures at 7.8” length, 4.31” width, and 1.22” height, in dimensional measurements, as intended load during the transport, sterilization and storage between their intended use. Similarly, Catalog #3709 measures at 6.32” length, 3.32” width, and 1.21” height, in dimensional measurements as intended load during the transport, sterilization and storage between their intended use. The ReNew Sterilization Tray (Catalog #3708 & 3709) have been validated with the ReNew Reusable Tips (Scissors, Graspers and Dissectors) wrapped in 2 layers of FDA-cleared 1-ply polypropylene wrap weighing a calculated total weight of 280.52 grams, for Catalog number 3708, and 148.195 grams for Catalog #3709. The validation included Cleaning Validation (Automated and Manual) Testing and Steam Sterilization Cycles. The validated prevacuum cycle parameters are as follows: time: 4 minutes at

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		temperature 132 °C, with a dry time of 30 minutes. The validated gravity cycle parameters are as follows: Time: 30 minutes at 121 °C with a dry time of 20 minutes, as well as time: 15 minutes at temperature 132 °C with a dry time of 20 minutes.
Technological Characteristics		
Primary Configuration	Plastic Tray	Plastic Tray
Primary Materials *(Construction)*	Polyphenylsulphone (Radel® R-5500) and Biomedical Grade Silicone.	Identical
Dimensions	**Lid:** 6.32" (Length) x 3.32" (Width) x 0.44" (Height) ±0.02 inches. **Base:** 6.15" (Length) x 3.14" (Width) x 0.77" (Height) inches.	Identical
Air Permeability	Yes	Yes
Intended for Reuse	Yes	Yes
Material Thickness	0.0625"	Identical
Hole Size	Lid: Ø.19, Base: Ø.175	Identical
Hole Pattern	**Lid:** Nine (9)X in Three (3) rows on bottom and top edges, Four (4)X evenly spaced in center of lid. **Base:** Nine (9)X in Three (3) rows [Centrally the lid includes the printed Company Logo and Trade Name].	Identical
Brackets	Two (2) rows - (.74)X(.29) with taper	Identical
Feet	Four (4) on base in corners (0.1955" height)	Identical
Weight	137 grams	Identical
Sterilization Method(s)	Wide Variety of Sterilization Methods applicable.	Steam Sterilization only
Sterilization Cycle Parameters	**Prevacuum Steam:** 132°C - 4 Mins Dry for 20 - 40 mins (as needed) **Gravity Air Displacement Cycle:** 132°C - 30 Mins **Gravity Steam:** 121°C - 55 Mins Dry for 20 - 50 mins (as needed)	**Pre vacuum Steam:** 132°C – 4 minutes Dry for 30 minutes **Gravity Steam:** 121°C – 30 minutes Dry for 20 minutes **Gravity Steam:** 132°C –15 minutes Dry for 20 minutes

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Sterility *(Disposable or Multiple Use)*	Multiple Use	Multiple Use
Patient Contact	No	No
Blood/Fluid Contact	No	No
Special Conditions *(Shipping and Handling)*	No	No
Manufacturer	**Contract Manufacturer:** Symmetry Medical, Inc. 253 Abby Road, Manchester, NH 03103 USA (Registration Number: 1221053) (Symmetry Medical OEM Solutions acquired by Tecomet, Inc., December 5, 2014)	Identical
Proposed Brand Labeling *(Relabeling, Repackaging and Market Distribution)*	Not Applicable	Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA
Differences in Technological Characteristics		
Tray Internal Configuration	Not Applicable	ReNew Sterilization Tray (Catalog #3709) internal configuration to secure the ReNew Tips (9 Tips configuration arrangement) only.

Performance Characteristics:

Microline Surgical, Inc., has successfully completed a full sterilization validation using Steam Sterilization method in accordance to AAMI TIR12:2010 - *Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities;* and EN ISO 17664:2004 - *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.* The acceptance criteria required that the sterilization methods demonstrate a sterility assurance level (SAL) of 10^{-6} using the biological indicator (BI) overkill method, which met as required. The sterilization validation testing and limits of reuse of the device, design tolerance analysis and shelf-life validation were completed. The subject devices ReNew Sterilization Tray (Catalog #3708 and #3709) are substantially equivalent to their respective predicate device, PolyVac Surgical Instrument Delivery System (K012105); in terms of fundamental technology, materials, design, meets the identical design inputs, and output requirements. The subject devices ReNew Sterilization Trays (Catalog #3708 and #3709) will be fully contract manufactured, assembled and packaged by contract manufacturer Symmetry Medical, Inc., (Registration Number: 1221053) located at 253 Abby Road, Manchester, NH 03103, USA., which is the same contract manufacturer for the predicate device. Any new validation testing including biocompatibility, bench testing and new validation or documentation, pertaining to design for manufacturing or design for assembly and packaging by Microline Surgical, Inc., were not deemed necessary.

Substantially Equivalent Conclusion:

Conclusively, based upon the similarities in fundamental technology, materials of construction and the intended use, Microline Surgical, Inc., has determined that the subject devices ReNew Sterilization Trays (Catalog #3708 and #3709) are deemed substantially equivalent (SE) to their legally marketed predicate device, PolyVac Surgical Instrument Delivery System (K012105). Similar to their predicate device, the subject devices ReNew Sterilization Trays (Catalog #3708 and

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#3709) are Class II devices per 21 CFR § 880.6850 (Product Code KCT) and under this classification category identified as Sterilization Wrap Containers, Trays, Cassettes & other Accessories. The subject devices ReNew Sterilization Tray (Catalog #3708 and #3709) do not raise new questions of safety and effectiveness; and demonstrate at least as safe and effective as their legally marketed predicate device (K012105).

Substantial Equivalence Statement:

The performance testing data for the subject devices ReNew Sterilization Tray (Catalog #3708 and #3709) demonstrates the subject devices are as safe, as effective, and performs as well as the predicate device (K012105).