



Food and Drug Administration
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February 8, 2016

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

Re: K152743

Trade/Device Name: M/L-10 Clip Applier Sterilization Tray (Catalog #3706)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: December 17, 2015
Received: December 18, 2015

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

Indications for Use

510(k) Number (if known)
K152743

Device Name
M/L- 10 Clip Applier Sterilization Tray (Catalog# 3706)

Indications for Use (Describe)

Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) is intended to protect the M/L-10 Clip Applier handpiece (Catalog #1002) 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 tray (Catalog# 3706) is maintained until used.

The Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) is used to secure the M/L-10 Clip Applier handpiece (Catalog #1002) which measures at 17.13" length, 4.94" height, and 0.90" width in dimensional measurements, as the intended load during the transport, sterilization and storage between its intended uses.

The M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) has been validated with the M/L-10 Clip Applier handpiece (Catalog #1002) wrapped in 2 layers of FDA-cleared 1-ply polypropylene wrap weighing a calculated total weight of 1663.10 grams. The M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) has been validated with the following Steam Sterilization Parameters: Pre-vacuum, Time: 4 minutes at Temperature of 132 °C. The Gravity Cycle parameters include: Time: 15 minutes and Temperature of 132 °C.

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]

K152743

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
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Date Prepared: February 1, 2016

Trade Name: M/L-10 Clip Applier Sterilization Tray
[Catalog # 3706]

Common Name: Sterilization Cassette

Classification: Class II, in accordance to 21 CFR § 880.6850
Sterilization Wrap Containers, Trays, Cassettes &
Other Accessories.

Classification Product Code(s): KCT

Regulation Medical Specialty: General Hospital

Predicate Device(s): C/T Med-Systems Cassette System (K980065)

Device Description:

Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog #3706) intended purpose is to secure the M/L-10 Clip Applier device during its transportation, sterilization, and storage purposes.

The subject device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) consists of a case, a cover and brackets. The M/L-10 Clip Applier Sterilization Tray (Catalog #3706) Lid is 19.875" (Length) x 5.632" (Width) x .450" (Height); and the Base is 19.875" (Length) x 5.50" (Width) x 1.450" (Height) in dimensions. The M/L-10 Clip Applier Sterilization Tray (Catalog #3706) cover and lid (case) are constructed of Stainless Steel material, which could be reused with Steam Sterilization method. The brackets are constructed from Aluminum, Stainless Steel, and biomedical grade Silicone. The M/L-10 Clip Applier Sterilization Tray surface is coated with Nylon Coating Powder. The sterilization tray cover is secured to the case by means of assembled hardware and a locking tab, designed as part of the cover. The case and cover have an evenly distributed hole pattern in relation to the tray size to support the steam sterilization process. The brackets are designed to secure the M/L-10 Clip Applier for sterilization purpose. The subject device M/L-10 Clip Applier Sterilization Tray is non-patient and non-blood/fluid contact during its intended use. The M/L-10 Clip Applier Sterilization

Tray (Catalog #3706) is a metal tray and packaged in bubble wrap, single wall, 32 lbs/inch edge, crushed corrugated brown cardboard shipping box, which does not need any special handling requirements during shipment.

Statement of Intended Use:

Indications for Use:

Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) is intended to protect the M/L-10 Clip Applier handpiece (Catalog #1002) 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 tray (Catalog# 3706) is maintained until used.

The Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) is used to secure the M/L-10 Clip Applier handpiece (Catalog #1002) which measures at 17.13" length, 4.94" height, and 0.90" width in dimensional measurements, as the intended load during the transport, sterilization and storage between its intended uses.

The M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) has been validated with the M/L-10 Clip Applier handpiece (Catalog #1002) wrapped in 2 layers of FDA-cleared 1-ply polypropylene wrap weighing a calculated total weight of 1663.10 grams. The M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) has been validated with the following Steam Sterilization Parameters: Pre-vacuum, Time: 4 minutes at Temperature of 132 °C. The Gravity Cycle parameters include: Time: 15 minutes and Temperature of 132 °C.

Contraindications:

The M/L-10 Clip Applier Sterilization Tray (3706) is not intended for use except as indicated.

Comparison to Predicate Device:

Microline Surgical, Inc., has determined substantial equivalence of the subject device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) with its legally marketed predicate device C/T Med-Systems Cassette System (K980065) based on the principles of safety and effectiveness applicable to the 510(k) review including the applicable standard and the least burdensome approach. The subject device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) is substantially equivalent to its predicate device C/T Med-Systems Cassette System (K980065) 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 device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) is the following:

- Internal configuration of the M/L-10 Clip Applier Sterilization Tray to secure the M/L-10 Clip Applier device.

In summary, the subject device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) is similar in its design, materials, manufacturing, performance, safety, effectiveness, labeling, sterilization, and fundamental technological characteristics as applicable to its legally marketed predicate device C/T Med-Systems Cassette System (K980065).

Summary of Technological Characteristics:

The Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog #3706) intended purpose is to secure the M/L-10 Clip Applier device during its transportation, sterilization, and storage purposes. The subject device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) is technologically similar to its legally marketed predicate device C/T Med-Systems Cassette System (K980065). The following pertains to the technological characteristics comparison presented in a tabular format.

| Characteristics | Predicate Device | Subject Device (Proposed) |
|-----------------------------------|--|---|
| Trade Name | C/T Med-Systems Cassette System | Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog #3706) |
| 510(k) Number | K980065 | This Submission |
| 510(k) Clearance Date | May 11, 1998 | 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. |
| Classification Product Code | KCT | KCT |
| Common Name | Sterilization Cassette | Sterilization Cassette |
| Regulation Medical Specialty | General Hospital | General Hospital |
| Environment of Use | Hospital, Operating Room (OR), Physician and dental office or place where instruments are sterilized. | Hospital, Operating Room (OR) Use only. |
| Intended Use (Indication for Use) | General dental/medical instrument cassettes intended to hold instruments and accessories in place throughout the entire instrument use, cleaning and sterilization cycle. These cassettes are suitable for Gravity Steam, Pre-vacuum steam and EO sterilization. | <p>Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) is intended to protect the M/L-10 Clip Applier handpiece (Catalog #1002) 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 tray (Catalog# 3706) is maintained until used.</p> <p>The Microline Surgical M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) is used to secure the M/L-10 Clip Applier handpiece (Catalog #1002) which measures at 17.13" length, 4.94" height, and 0.90" width in dimensional measurements, as the intended load during the transport, sterilization and storage between its intended uses.</p> <p>The M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) has been</p> |

| | | validated with the M/L-10 Clip Applier handpiece (Catalog #1002) wrapped in 2 layers of FDA-cleared 1-ply polypropylene wrap weighing a calculated total weight of 1663.10 grams. The M/L-10 Clip Applier Sterilization Tray (Catalog# 3706) has been validated with the following Steam Sterilization Parameters: Pre-vacuum, Time: 4 minutes at Temperature of 132 °C. The Gravity Cycle parameters include: Time: 15 minutes and Temperature of 132 °C. |
|---|---|--|
| Technological Characteristics | | |
| Primary Configuration | Metal Tray | Metal Tray |
| Primary Materials (Construction) | Stainless Steel and Aluminum Tray Coating: Nylon Coating Powder | Stainless Steel, Aluminum and Biomedical Grade Silicone. Tray Coating: Nylon Coating Powder |
| Dimensions | Lid: 19.875" (Length) x 5.632" (Width) x .450" (Height) inches Base: 19.875" (Length) x 5.50" (Width) x 1.450" (Height) inches | Identical |
| Air Permeability | Yes | Yes |
| Intended for Reuse | Yes | Yes |
| Material Thickness | .036" | Identical |
| Hole Size | Ø 0.250" | Identical |
| Hole Pattern | Lid: Six (6) rows evenly spaced with Twenty-five (25) Holes, with Fifty (50) centrally removed to account for the Company Logo and Trade Name. Base: Six (6) rows evenly spaced with Twenty-five (25) Holes, with Twenty-one (21) removed to account for the brackets. | Identical |
| Brackets | Two (2) Silicone, Two (2) Stainless Steel and One (1) Aluminum. | Identical |
| Feet | None | None |
| Weight | 1663.10 grams | Identical |
| Sterilization Method(s) | Steam Sterilization & Ethylene Oxide (EtO) | Steam Sterilization only |
| Sterilization Cycle Parameters | Prevacuum Steam: 132°C – 4 minutes Dry for 20 minutes Gravity Steam: 132°C –15 minutes Dry for 30 minutes | Prevacuum Steam: 132°C – 4 minutes Dry for 20 minutes Gravity Steam: 132°C –15 minutes Dry for 45 minutes |

| | | |
|--|--|--|
| Sterility <i>(Disposable or Multiple Use)</i> | Multiple Use | Multiple Use |
| Patient Contact | No | No |
| Blood/Fluid Contact | No | No |
| Special Conditions <i>(Shipping and Handling)</i> | No | No |
| Manufacturer | Contract Manufacturer: MEDIN Corporation 11 Jackson Road, Totowa, NJ 07512 USA (Registration Number: 3011296511) | Identical |
| Proposed Brand Labeling <i>(Relabeling, Repackaging and Market Distribution)</i> | Not Applicable | Microline Surgical, Inc. 50 Dunham Road, Suite 1500 Beverly, MA 01915 USA |
| Differences in Technological Characteristics | | |
| Tray Internal Configuration | Not Applicable | M/L-10 Clip Applier Sterilization Tray internal configuration to secure the M/L-10 Clip Applier device 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 device M/L-10 Clip Applier Sterilization Tray (Catalog #3706), is substantially equivalent to its predicate device in terms of fundamental technology, materials and design and meets the identical design inputs and output requirements. As the subject device, M/L-10 Clip Applier Sterilization Tray (Catalog #3706) will be fully contract manufactured, assembled and packaged by contract manufacturer MEDIN Corporation (Registration Number: 3011296511), any new validation testing including biocompatibility, bench testing including 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 device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) is deemed substantially equivalent (SE) to its legally marketed predicate device C/T Med-Systems Cassette System (K980065). Similar to its predicate device, the subject device M/L-10 Clip Applier Sterilization Tray is a Class II device per 21 CFR § 880.6850 (Product Code KCT) and under this classification category identified as Sterilization Wrap Containers, Trays, Cassettes & other Accessories. The subject device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) does not raise new questions of safety and effectiveness; and demonstrates at least as safe and effective as its legally marketed predicate device.



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Substantial Equivalence Statement:

The performance testing data for the subject device M/L-10 Clip Applier Sterilization Tray (Catalog #3706) demonstrates the subject device is as safe, as effective, and performs as well as the predicate device (K980065).