May 7, 2021

Karl Storz Endoscopy America Inc
% David Furr
Consultant
Toscano Consulting Group Inc.
8708 Capeheart Cove
Austin, Texas 78733

Re: K203572
Trade/Device Name: Karl Storz Radel Sterilization Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: April 15, 2021
Received: April 19, 2021

Dear David Furr:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Clarence W. Murray, III, Ph.D.
Acting Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203572

Device Name
KARL STORZ RADEL Sterilization Trays

Indications for Use *(Describe)*

The KARL STORZ RADEL Sterilization Trays are intended only for use to encase and protect specific KARL STORZ reusable medical devices for sterilization in pre-vacuum steam sterilization cycles (132ºC 4 minutes).

The KARL STORZ RADEL Sterilization Trays are intended to protect medical device instrumentation. When used in conjunction with an FDA cleared sterilization wrap.

KARL STORZ has validated the KARL STORZ RADEL Sterilization Trays for use in pre-vacuum steam sterilizers. The system was validated with a miniature scope with an irrigation channel lumen diameter of 0.25mm and a length of 240mm and a semi-rigid ureteroscope with a channel lumen diameter of 0.77mm and a length of 420mm.

Tray Catalog Number	Intended Load Maximum Weight (Karl Storz Instruments Only)
27717A	Trocar/Cannula 5.0 lbs.
27717B	Take-Apart Instruments 5.0 lbs.
39231XA	Karl Storz General Instruments 5.0 lbs.
39301A	Two Rigid Telescopes 2.71lbs.
39301C	Two Rigid Telescopes 3.21lbs.
39301C1	One Rigid Telescope/One Light Cable 3.17 lbs.
39311A	Four Telescopes/One Light Cable 6.86 lbs.
39317A	Three Telescopes/One Light Cable 6.86 lbs.

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 K203572

Date: May 5, 2021

1. Submitted By: KARL STORZ Endoscopy-America, Inc.
2151 E. Grand Ave.
El Segundo, California 90245
424-218-8376

2. Contact: David C. Furr
Toscano Consulting Group Inc.
8708 Capehart Cove
Austin, Texas 78733
512-906-9654

3. Product: KARL STORZ RADEL Sterilization Trays (K203572)
Product code: KCT - Class II (21 CFR 880.6850)

4. Common/Classification
Name: Sterilization wrap/container
Predicate devices: Symmetry Medical Polyvac Surgical Instrument Delivery System K012105

Description:

The KARL STORZ-ENDOSCOPE RADEL Sterilization Trays are intended only for use to encase various KARL STORZ reusable medical devices for sterilization in steam cycles. The sterilization trays are not intended to maintain sterility by themselves. Prior to sterilization, the trays must be double-wrapped with an appropriate FDA-cleared sterilization wrap to provide a microbial barrier which allows sterilant to permeate throughout the interior of the loaded tray.

The tray configurations, available in various sizes, are designed to encase KARL STORZ medical devices, such as light cables, instruments, rigid telescopes, semi-rigid telescopes, etc. All systems consist of a RADEL plastic base and lid. Lids are attached to the trays with assembled hardware. Some trays have a RADEL inner tray and/or silicone rubber mat.

The sterilization trays are constructed with perforated/ventilated sides and lids to allow for permeation of sterilant during sterilization. The trays have latches designed to fasten the lid onto the base. Other tray components include silicone instrument holders to secure instruments and silicone mats to provide protection of the medical devices in the sterilization tray.

Intended Use:

The KARL STORZ RADEL Sterilization Trays are intended only for use to encase and protect specific KARL STORZ reusable medical devices for sterilization in pre-vacuum steam sterilization cycles (132ºC 4 minutes).

The trays are to be used in conjunction with an FDA cleared sterilization wrap.

KARL STORZ has validated the KARL STORZ RADEL Sterilization Trays for use in pre-vacuum steam sterilizers. The system was validated with a miniature scope with an irrigation channel lumen diameter of 0.25mm and a length of 240mm and a semi-rigid ureteroscope with a channel lumen diameter of 0.77mm and a length of 420mm.

Tray Catalog Number	Intended Load Maximum Weight (Karl Storz Instruments Only)
27717A	Trocar/Cannula 5.0 lbs.
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39301C1	One Rigid Telescope/One Light Cable 3.17 lbs.
39311A	Four Telescopes/One Light Cable 6.86 lbs.
39317A	Three Telescopes/One Light Cable 6.86 lbs.

Technological Characteristics Comparison Table:

Provided below is the comparison of the technological differences and similarities of the subject device and the predicate device.

Element of Comparison	**510(k) Device: KARL STORZ RADEL Sterilization Trays**	**Predicate Device:** Symmetry Medical Polyvac Surgical Instrument Delivery System (K012105)	**Comparison**
Regulation and Product Classification Code	21 CFR 880.6850 KCT	21 CFR 880.6850 KCT	Same
Indications for Use	The KARL STORZ RADEL Sterilization Trays are intended only for use to encase and protect specific KARL STORZ reusable medical devices for sterilization in pre-vacuum steam sterilization cycles (132ºC 4 minutes). When used in conjunction with an FDA cleared sterilization wrap, sterility of the enclosed medical device is maintained until used. KARL STORZ has validated the KARL STORZ RADEL Sterilization Trays for use in pre-vacuum steam sterilizers. The system was validated with a miniature scope with an irrigation channel lumen diameter of 0.25mm and a length of 240mm and a semi-rigid ureteroscope with a channel lumen diameter of 0.77mm and a length of 420mm.	Polyvac's Delivery Systems consist of perforated trays with lids, which are intended to enclose and protect medical device instrumentation, and to facilitate the sterilization processing by allowing steam penetration and air removal, when used in conjunction with an approved sterilization wrap. Sterility of the enclosed medical devices maintained until used. Polyvac's Delivery Systems are to be sterilized in one of the following cycles: pre vacuum steam, 132ºC 4 minutes minimum, gravity steam 132ºC 30 minutes minimum and gravity steam 121ºC 55 minutes minimum.	Similar
Principal Material of Construction	Thermoformed Radel Polyphenylsulfone,	Thermoformed Radel Polyphenylsulfone, stainless steel or aluminum	Different

KARL STORZ Model Numbers	8 models • 27717A • 27717B • 39231XA • 39301A • 39301C • 39301C1 • 39311A • 39317A	N/A	Different
Dimensional Configuration Range	Approximate sizes available in inches: • 21.2x9.8x4.3 • 21.2x9.8x1.9 • 19.8x8.9x1.8 • 12.18x3.22x1.2 • 21.48 x 3.53x 1.75 • 21.48 x 3.53x 1.75 • 13.36 x 9.31x 1.9 • 20.24x9.30x3.1	Approximate sizes available in inches: • 7x2x1 • 7x3x1 • 8x4x1 • 11x7x1 • 21x10x4 • 17x10x4 • 17x8x2 • 15x10x1.5 • 20.5x9.7x5 • 20x10x3 • 26x9x6 • 17x3.5x1.5 • And others	Similar
Device Manufacturer	Manufactured by Tecomet (formerly Symmetry Medical)	Manufactured by Tecomet (formerly Symmetry Medical)	Same
Sterilization Cycles	Prevacuum Steam 4 minute cycle 132ºC	Prevacuum steam and gravity steam	Similiar
Load	Trays are to be loaded with KARL STORZ instruments; maximum weights as indicated	Various loads up to 25 lbs.	Similar

Summary of Non-Clinical Testing:

Shown below is the non-clinical testing performed with the subject device and the standards and test method used to demonstrate the subject device met the acceptance criteria of each standard..

Type of Testing	Purpose	Acceptance Criteria	Result
Pre-vacuum sterilization efficacy AAMI ST77 Containment Devices for Reusable Medical Device Sterilization ISO 17665-1 Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	Demonstrate sterilization capabilities.	10^{-6} SAL	PASSED
Pre-vacuum dry time AAMI ST77 Containment Devices for Reusable Medical Device Sterilization ISO 17665-1 Sterilization of Health Care Products – Moist Heat – Part 1 Requirements for the Development, Validation, and Routine Control of a Sterilization Process for Medical Devices	To establish minimum dry time.	Pre and Post Sterilization weight difference <3% after drying	PASSED 30 minutes dry time
Manual Cleaning – Protein, Hemoglobin AAMI TIR 30 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices	To demonstrate manual cleaning	< 6.4 µg/cm^2 protein and < 2.2 µg/cm^2 hemoglobin on device after cleaning	PASS
Mechanical Cleaning – Protein, Hemoglobin AAMI TIR 30 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices	To demonstrate mechanical cleaning	< 6.4 µg/cm^2 protein and < 2.2 µg/cm^2 hemoglobin on device after cleaning	PASS

Material biocompatibility ISO 10993-5 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro cytotoxicity	To demonstrate no Cytotoxic properties	Cytotoxicity – No evidence of lysis	PASS

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the subject device is as safe, as effective, and performed as well as or better than the legally marketed predicate devices.