February 25, 2021

Karl Storz EndoscopyAmerica Inc
% David Furr
Consultant
Toscano Consulting
8708 Capehart Cove
Austin, Texas 78733

Re: K201945
Trade/Device Name: KARL STORZ UDEL Sterilization Trays
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: January 26, 2021
Received: January 28, 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,

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201945

Device Name
KARL STORZ UDEL Sterilization Trays

Indications for Use *(Describe)*
The KARL STORZ UDEL Sterilization Trays are intended only for use to encase and protect specific KARL STORZ reusable medical devices for sterilization in STERRAD and steam sterilization systems as indicated in the attached table. The system may be used with flexible endoscopes with lumen diameters ≥ 1.2mm and a maximum length of 845mm. KARL STORZ UDEL Sterilization Trays must be used in conjunction with an FDA cleared sterilization wrap or container.

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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Tray Name	Intended Content KARL STORZ Instruments Only	STERRAD® 100S	STERRAD® NX		STERRAD® 100NX		Steam Pre-vacuum 132ºC 4 minutes See Dry Time in Table	Steam Gravity Cycle 121ºC 30 minutes See Dry Time in Table	Product Load and Maximum Weight
			Standard Cycle	Advanced Cycle	Standard Cycle	Flex Cycle			
Flexible Endoscope Tray, P/N 39401AS	Flexible Endoscope	✓ Non-Lumen Only		Note: Tray does not fit chamber		✓	Note: Flexible endoscopes cannot be autoclaved	Note: Flexible endoscopes cannot be autoclaved	1 flexible fiberscope 5.76 lbs.
Flexible Endoscope Tray, P/N 39402AS	Flexible Endoscope	✓ Non-Lumen Only		✓		✓	Note: Flexible endoscopes cannot be autoclaved	Note: Flexible endoscopes cannot be autoclaved	1 flexible fiberscope 1 fiber optic light cable 8.18 lbs.
Flexible Video Endoscope Tray, P/N 39403AS	Flexible CCD Video Endoscope	✓ Non-Lumen Only		✓		✓	Note: Flexible video endoscopes cannot be autoclaved	Note: Flexible video endoscopes cannot be autoclaved	1 flexible CCD video endoscope 5.28 lbs.
Flexible Endoscope Tray, P/N 39406AS	Flexible CMOS Video Endoscope	✓ Non-Lumen Only		✓		✓	Note: Flexible video endoscopes cannot be autoclaved	Note: Flexible video endoscopes cannot be autoclaved	1 flexible CMOS video endoscope 5.23 lbs.
Camera Trays P/N 39301HCTS P/N 39301PHTS P/N 39301BCTS	Non-autoclave-able camera heads	✓	✓		✓		Note: Steam is not indicated when used with non-autoclavable camera heads	Note: Steam is not indicated when used with non-autoclavable camera heads	1 camera head 2.82 lbs (HCTS) 2.64 lbs. (PHTS) 4.32 lbs. (BCTS)
Camera Trays P/N 39301HCTS P/N 39301ACTS P/N 39301PHTS	Autoclave-able camera heads	✓	✓		✓		✓ Minimum Dry Time 50 minutes	✓ Minimum Dry Time 80 minutes	1 camera head 2.82 lbs (HCTS) 3.08 lbs. (ACTS) 2.64 lbs. (PHTS)
Rigid Telescope Trays P/N 39301AS P/N 39301BS P/N 39301CS P/N 39301DS	Rigid Telescopes (Non-Lumen only)	✓	✓		✓		✓ Minimum Dry Time 30 minutes	✓ Minimum Dry Time 80 minutes	2 Telescopes 2.71 lbs. (AS) 3.21 lbs. (CS) 3.71 lbs. (DS) 4 Telescopes 6.86 lbs. (BS)
Rigid Telescope Tray P/N 39301C1S	Rigid Telescopes (Non-Lumen only)	✓	✓		✓		✓ Pre-Vacuum Only Minimum Dry Time 30 minutes		1 rigid telescope 1 fiber optic cable 3.17 lbs.
Rigid Telescope Trays P/N 39311AS P/N 39314FS	Rigid Telescopes (Non-Lumen only)	✓	✓		✓		✓ Pre-Vacuum Only Minimum Dry Time 30 minutes		4 rigid telescopes 1 fiber optic cable 6.86 lbs. (AS) 8.12 lbs. (FS)
Rigid Telescope Tray, P/N 39311BS	Rigid Telescopes (Non-Lumen Only)	✓	✓		✓		✓ Pre-Vacuum Only Minimum Dry Time 30 minutes		2 rigid telescopes 1 fiber optic cable 4.9 lbs.
Basket-Style Rigid Telescope Trays P/N 39305C1S P/N 39305C2S P/N 39305L1S P/N 39305L2S	Rigid Telescopes (Non-Lumen only)	✓	✓		✓		✓ Pre-Vacuum Only Minimum Dry Time 30 minutes		1 rigid telescope 1.58 lbs (C1S) 1.58 lbs (L1S) 2 rigid telescopes 2.56 lbs. (C2S) 2.56 lbs. (L2S)

510(k) Summary – K201945

Date: February 24, 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 UDEL Sterilization Trays
Product code: KCT - Class II (21 CFR 880.6850)

4. Common/Classification
Name: Sterilization wrap/container
Predicate devices: KARL STORZ- Endoscope Sterilization Trays K090818
Symmetry Medical Polyvac Surgical Instrument Delivery System K012105

Description:

The KARL STORZ UDEL Sterilization Trays are intended only for use to encase specific KARL STORZ reusable medical devices for sterilization in steam and specified STERRAD Sterilization System 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 specific KARL STORZ medical devices, such as fiber optic light cable, flexible endoscopes, rigid telescopes, and camera heads. Some of the trays are specifically molded to fit and accommodate KARL STORZ light cables, flexible endoscopes, camera heads and rigid telescopes, allowing the instruments to be arranged in an organized manner when placed in the tray. All systems consist of a Udel plastic base and Udel plastic lid. Lids are attached to the trays with assembled hardware. Baskets are injection molded and trays are thermoformed from Udel polysulfone polymer (sourced from Solvay Specialty Polymers), which is compatible with all indicated sterilization modes.

The sterilization trays are constructed with a perforated lid and base to allow for permeation of sterilant during sterilization. Some of the tray configurations are simply molded into the form of a mesh. The trays have latches designed to fasten the lid onto the base. Other tray components include silicone holders and mats (depending on the tray type) to secure instruments and provide protection of the medical devices in the sterilization tray. The holders and mats are manufactured from silicone material, which is also compatible with all sterilization modes.

510(k) Premarket Notification
KARL STORZ UDEL Sterilization Trays

Intended Use:

The KARL STORZ UDEL Sterilization Trays are intended only for use to encase and protect specific KARL STORZ reusable medical devices for sterilization in STERRAD and steam sterilization systems as indicated in the attached table. The system may be used with flexible endoscopes with lumen diameters ≥ 1.2mm and a maximum length of 845mm.

KARL STORZ UDEL Sterilization Trays must be used in conjunction with an FDA cleared sterilization wrap or container.

Tray Name	Intended Content KARL STORZ Instruments Only	STERRAD® 100S	STERRAD® NX		STERRAD® 100NX		Steam Pre-vacuum 132ºC 4 minutes See Dry Time in Table	Steam Gravity Cycle 121ºC 30 minutes See Dry Time in Table	Product Load and Maximum Weight
			Standard Cycle	Advanced Cycle	Standard Cycle	Flex Cycle			
Flexible Endoscope Tray, P/N 39401AS	Flexible Endoscope	✓ Non-Lumen Only		Note: Tray does not fit chamber		✓	Note: Flexible endoscopes cannot be autoclaved	Note: Flexible endoscopes cannot be autoclaved	1 flexible fiberscope 5.76 lbs.
Flexible Endoscope Tray, P/N 39402AS	Flexible Endoscope	✓ Non-Lumen Only		✓		✓	Note: Flexible endoscopes cannot be autoclaved	Note: Flexible endoscopes cannot be autoclaved	1 flexible fiberscope 1 fiber optic light cable 8.18 lbs.
Flexible Video Endoscope Tray, P/N 39403AS	Flexible CCD Video Endoscope	✓ Non-Lumen Only		✓		✓	Note: Flexible video endoscopes cannot be autoclaved	Note: Flexible video endoscopes cannot be autoclaved	1 flexible CCD video endoscope 5.28 lbs.
Flexible Endoscope Tray, P/N 39406AS	Flexible CMOS Video Endoscope	✓ Non-Lumen Only		✓		✓	Note: Flexible video endoscopes cannot be autoclaved	Note: Flexible video endoscopes cannot be autoclaved	1 flexible CMOS video endoscope 5.23 lbs.
Camera Trays P/N 39301HCTS P/N 39301PHTS P/N 39301BCTS	Non-autoclave-able camera heads	✓	✓		✓		Note: Steam is not indicated when used with non-autoclavable camera heads	Note: Steam is not indicated when used with non-autoclavable camera heads	1 camera head 2.82 lbs (HCTS) 2.64 lbs. (PHTS) 4.32 lbs. (BCTS)
Camera Trays P/N 39301HCTS P/N 39301ACTS P/N 39301PHTS	Autoclave-able camera heads	✓	✓		✓		✓ Minimum Dry Time 50 minutes	✓ Minimum Dry Time 80 minutes	1 camera head 2.82 lbs (HCTS) 3.08 lbs. (ACTS) 2.64 lbs. (PHTS)
Rigid Telescope Trays P/N 39301AS P/N 39301BS P/N 39301CS P/N 39301DS	Rigid Telescopes (Non-Lumen only)	✓	✓		✓		✓ Minimum Dry Time 30 minutes	✓ Minimum Dry Time 80 minutes	2 Telescopes 2.71 lbs. (AS) 3.21 lbs. (CS) 3.71 lbs. (DS) 4 Telescopes 6.86 lbs. (BS)
Rigid Telescope Tray P/N 39301C1S	Rigid Telescopes (Non-Lumen only)	✓	✓		✓		✓ Pre-Vacuum Only Minimum Dry Time 30 minutes		1 rigid telescope 1 fiber optic cable 3.17 lbs.
Rigid Telescope Trays P/N 39311AS P/N 39314FS	Rigid Telescopes (Non-Lumen only)	✓	✓		✓		✓ Pre-Vacuum Only Minimum Dry Time 30 minutes		4 rigid telescopes 1 fiber optic cable 6.86 lbs. (AS) 8.12 lbs. (FS)
Rigid Telescope Tray, P/N 39311BS	Rigid Telescopes (Non-Lumen Only)	✓	✓		✓		✓ Pre-Vacuum Only Minimum Dry Time 30 minutes		2 rigid telescopes 1 fiber optic cable 4.9 lbs.
Basket-Style Rigid Telescope Trays P/N 39305C1S P/N 39305C2S P/N 39305L1S P/N 39305L2S	Rigid Telescopes (Non-Lumen only)	✓	✓		✓		✓ Pre-Vacuum Only Minimum Dry Time 30 minutes		1 rigid telescope 1.58 lbs (C1S) 1.58 lbs (L1S) 2 rigid telescopes 2.56 lbs. (C2S) 2.56 lbs. (L2S)

Comparison of Technological Characteristics:

The KARL STORZ UDEL Sterilization Trays are intended to protect medical device instrumentation and facilitate the sterilization process by sterilant penetration and air removal.

The KARL STORZ UDEL Sterilization Trays are predicated on the original KARL STORZ Endoskope Sterilization Trays (K090818). Three of the devices, 39301HCTC, 39402AS and 39301BS, are identical to this predicate with the exception of additional indications. In addition the Symmetry Medical Polyvac Surgical Instrument Delivery System (K012105) is included as a predicate for steam applications.

Tray configurations and loads are the same as the devices which were included in KARL STORZ previous 510(k) K090818. Additional tray configurations have been added and validated based on comparison of worst-case vent to volume factors and load.

Sterilant enters the KARL STORZ UDEL sterilization trays through perforations in the tray base and lid. After sterilization, sterility is maintained by an FDA cleared sterilization wrap. All of these characteristics are the same as the predicate devices.

All trays including all the predicate devices are manufactured by the same supplier using the same manufacturing processes.

510(k) Premarket Notification
KARL STORZ UDEL Sterilization Trays

Element of Comparison	**510(k) Device: KARL STORZ UDEL Sterilization Trays**	**Predicate Device:** KARL STORZ Endoskope Sterilization Trays (K090818)	**Predicate Device:** Symmetry Medical Polyvac Surgical Instrument Delivery System (K012105)	**Explanation of Differences**
Regulation and Product Classification Code	21 CFR 880.6850 KCT	21 CFR 880.6850 KCT	21 CFR 880.6850 KCT	None
Indications for Use	The KARL STORZ UDEL Sterilization Trays are intended only for use to encase and protect specific KARL STORZ reusable medical devices for sterilization in STERRAD and steam sterilization systems as indicated in the attached table. The system may be used with flexible endoscopes with lumen diameters ≥ 1.2mm and a maximum length of 845mm. KARL STORZ UDEL Sterilization Trays must be used in conjunction with an FDA cleared sterilization wrap or container.	The KARL STORZ Endoskope Sterilization Trays are intended only for use to encase and protect specific KARL STORZ reusable medical devices for sterilization in STERRAD 100S and NX sterilization systems as indicated. STERRAD Sterilization Systems are pre-set and cycle parameters cannot be adjusted. Table 1 provides sterilization compatibility for STERRAD Sterilization Cycles and max load with KARL STORZ-Endoskope Sterilization Trays & Instruments. (Table provided in IFU)	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.	The new system can be used for any of the three sterilization methods cited in the predicates. The new indications for use includes all three methods.
Principal Material of Construction	Thermoformed or injection molded Udel Polysulfone	Thermoformed or injection molded Udel Polysulfone	Thermoformed Radel Polyphenylsulfone or aluminum	Udel trays are made from the identical material as the KARL STORZ predicate; Most Symmetry Medical predicates are made from Radel, a similarly performing polymer in steam cycles

510(k) Premarket Notification
KARL STORZ UDEL Sterilization Trays

Element of Comparison	**510(k) Device: KARL STORZ UDEL Sterilization Trays**	**Predicate Device:** KARL STORZ Endoskope Sterilization Trays (K090818)	**Predicate Device:** Symmetry Medical Polyvac Surgical Instrument Delivery System (K012105)	**Explanation of Differences**
KARL STORZ Model Numbers	20 models • 39301PHTS • 39301HCTS • 39301ACTS • 39301BCTS • 39401AS • 39402AS • 39403AS • 39406AS • 39311BS • 39301DS • 39314FS • 39311AS • 39301C1S • 39301CS • 39301AS • 39301BS • 39305C1S • 39305C2S • 39305L1S • 39305L2S	3 models • 39301HCTS • 39402AS • 39301BS	N/A	Additional models have been added for this submission. Symmetry Medical model numbers from previous submissions are not related.
Dimensional Configuration Range	Approximate sizes available in inches (see product description chart **Section 4.2** for exact dimensions by catalog number): • 15x10x2.5 • 27x7x4 • 21x10x4 • 21x10x3 • 26x4x3 • 20x9x4 • 13x9x2 • 21x3.5x2 • 12x3.5x2 • 17x3.5x2 • 19x4x9	Approximate sizes available in inches: • 15x10x2.5 • 22x10x4 • 17x3.5x2	Approximate sizes available in inches: • 7x2x1 • 7x3x1 • 8x4x1 • 11x7x1 • 21x10x4 • 17x10x4 • 17x8x2 • 15x10x1.5 • 20.5x9.7x5 • 20x10x3 • 26x9x6 • 17x3.5x1.5 • And others	3 of the KARL STORZ trays are identical to the KARL STORZ predicate and the others fall into very similar size ranges.
Device Manufacturer	Contract manufactured for KARL STORZ by Tecomet	Contract manufactured for KARL STORZ by Tecomet	Manufactured by Tecomet (formerly Symmetry Medical)	None. All trays are manufactured in the same location by Tecomet
Sterilization Cycles	Prevacuum Steam 4 minute cycle 132ºC, Gravity Steam 30 mins 121 ºC STERRAD 100S, NX, and 100NX cycles	STERRAD 100S, NX, and 100NX cycles	Prevacuum Steam and Gravity Steam Cycles	Subject device can be used in the predicate device cycles as specified in the Indications.
Load	Trays are to be loaded with specific KARL STORZ instruments	Trays are to be loaded with specific KARL STORZ instruments	Various loads up to 25 lbs.	KARL STORZ trays are used with specific instruments and Symmetry predicates are general use.

Summary of Non-Clinical Testing:

The following testing was conducted or is referenced to establish efficacy. Worst case tray configurations were used to represent all trays.

Type of Testing	Primary Standard(s) Used (as applicable)	Test Criteria and Result
STERRAD 100S sterilization efficacy	AAMI ST77 Containment Devices for Reusable Medical Device Sterilization ISO 14937 Sterilization of Health Care Products – General Requirements for the Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	10^{-6} SAL PASSED
STERRAD NX standard and advanced cycle sterilization efficacy	AAMI ST77 Containment Devices for Reusable Medical Device Sterilization ISO 14937 Sterilization of Health Care Products – General Requirements for the Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	10^{-6} SAL PASSED
STERRAD 100NX flex cycle sterilization efficacy	AAMI ST77 Containment Devices for Reusable Medical Device Sterilization ISO 14937 Sterilization of Health Care Products – General Requirements for the Characterization of a Sterilizing Agent and the Development, Validation and Routine Control of a Sterilization Process for Medical Devices	10^{-6} SAL PASSED
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	10^{-6} SAL PASSED

510(k) Premarket Notification
KARL STORZ UDEL Sterilization Trays

Type of Testing	Primary Standard(s) Used (as applicable)	Test Result
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	Establish Minimum Dry Time ESTABLISHED
Gravity 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	10^{-6} SAL PASSED
Gravity 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	Establish Minimum Dry Time ESTABLISHED
Manual Cleaning – Protein, Hemoglobin	AAMI TIR 30 A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices	< 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	< 6.4 µg/cm^2 protein and < 2.2 µg/cm^2 hemoglobin on device after cleaning PASS
Material biocompatibility	ISO 10993 Biological Evaluation of Medical Devices	Cytotoxicity – No evidence of lysis PASS
Material stability 200 STERRAD Cycles and 2100 Steam Cycles	Internal Protocols and AAMI TIR 12 Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities	Material Maintains Integrity PASS

Conclusion:

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