DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 21, 2016

CareFusion 2200 Inc.
Ms. Jane Weber
Manager, Regulatory Affairs
75 N. Fairway Drive
Vernon Hills, Illinois 60061

Re: K153554
Trade/Device Name: Genesis™ Low Temperature Reusable Rigid Container System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: February 22, 2016
Received: February 23, 2016

Dear Ms. Jane Weber:

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" (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 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 on last page.

510(k) Number *(if known)*
K153554

Device Name
Genesis(TM) Low Temperature Reusable Rigid Sterilization Container System

Indications for Use *(Describe)*
The Genesis(TM) Low Temperature Reusable Rigid Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed device until used for a maximum of 180 days.

Containers are suitable for various STERRAD and V-PRO low temperature sterilization modalities when used as described in the instructions for use.

Reusable baskets and accessory items (pins, dividers, mats, etc.) are intended to organize and secure enclosed medical devices during sterilization and storage of the container.

Data cards are used to record information regarding a specific sterilization process load. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow contains a modality-specific external process indicator that serves as a visual indication that the system has been exposed to a specific sterilization cycle parameter. Data cards, filters and tamper evident arrows are single use only.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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K153554 INDICATIONS FOR USE

Sterilization Cycle Parameters for the Genesis Low Temperature Reusable Rigid Container System by Modality

Sterilization Cycle Parameters	Load Configuration	
	Total System Weight	**Applicable Containers / Accessories**
STERRAD NX Standard Push button cycle with non-adjustable parameters	10.7 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Lumen Devices (1.0 mm x 150 mm) Stainless Steel, Qty. 10 Lumen Devices (2.0 mm x 400 mm) Stainless Steel, Qty. 10 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD NX
STERRAD NX Advanced Push button cycle with non-adjustable parameters	10.7 lbs. (Endoscope load: no additional load)	Perforated Bottom Low Temperature Containers; Stacking Baskets Lumen Devices (1.0 mm x 150 mm) Stainless Steel, Qty. 10 Lumen Devices (2.0 mm x 400 mm) Stainless Steel, Qty. 10 Lumen Devices (1.0 mm x 500 mm) Stainless Steel, Qty. 10 Lumen Devices (1.0 mm x 850 mm) PE/PTFE, Qty. 1 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD NX
STERRAD 100NX Standard Push button cycle with non-adjustable parameters	21.4 lbs.	Perforated Bottom Low Temperature Containers; Stacking baskets Lumen Devices (0.7 mm x 500 mm) Stainless Steel, Qty. 10 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD 100NX
STERRAD 100NX Flex Push button cycle with non-adjustable parameters	No additional load	Perforated Bottom Low Temperature Containers; Lumen Devices (1.0 mm x 850 mm) PE/PTFE, Qty. 2 Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD 100NX
STERRAD 100NX Express Push button cycle with non-adjustable parameters	10.7 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD 100NX

K153554 INDICATIONS FOR USE

Sterilization Cycle Parameters	Load Configuration	
	Total System Weight	**Applicable Containers / Accessories**
V-PRO 1 Plus maX Non-Lumen Push button cycle with non-adjustable parameters	19.65 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO
V-PRO 1, 1 Plus maX Lumen Push button cycle with non-adjustable parameters	19.65 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Single Channel (0.77 mm x 500mm) Stainless Steel; Dual channel (0.77 mm x 527mm) Stainless Steel; Triple Channel (1.2 mm x 275 mm, 1.8 mm x 310 mm, 2.8 mm x 317 mm) Stainless Steel; Max 20 lumens per load Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO
V-PRO maX Flexible Push button cycle with non-adjustable parameters	2 scopes, or One scope + instruments for total of 24.0 lbs.	Perforated Bottom Low Temperature Containers; Flexible Endoscopes – Qty. 2 w/ no additional load; Qty. 1 w/ instrument load for 24 lbs total Single Lumen (1 mm x 1050mm) or Two lumens, one (1 mm x 998 mm) the other (1 mm x 850 mm) Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO
V-PRO 60 Non-Lumen Push button cycle with non-adjustable parameters	12.0 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO 60
V-PRO 60 Lumen Push button cycle with non-adjustable parameters	11.0 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Single Channel (0.77 mm x 410 mm) Stainless Steel; Dual Channel (0.77 mm x 410 mm) Stainless Steel; Triple Channel (1.2 mm x 275 mm, 1.8 mm x 310 mm, 2.8 mm x 317 mm) Stainless Steel; Max 12 lumens per load Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO 60

K153554 INDICATIONS FOR USE

Sterilization Cycle Parameters	**Load Configuration**	
	Total System Weight	**Applicable Containers / Accessories**
V-PRO 60 Flexible Push button cycle with non-adjustable parameters	No additional load	Perforated Bottom Low Temperature Containers; Flexible Endoscopes, Qty. 1 Single Lumen (1.0 mm x 990 mm) or Two Lumens (1.0 mm x 990 mm) Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO 60
Examples of instrument types that are conjoined include: a lumen secured to a silicone bar, an instrument placed on a silicone mat, a double action instrument with mated parts held open. Note: Air tight occluded challenges - devices with surfaces that are completely obstructed - have **not** been validated for use in the Genesis Low Temperature Reusable Sterilization Container System. *Materials: For examples of materials supported in the STERRAD NX, STERRAD 100NX, V-PRO 1, V-PRO 1 Plus, V-PRO maX, and V-PRO 60 sterilization modalities, please refer to the corresponding Instructions for Use from the sterilizer manufacturer.		

K153554 INDICATIONS FOR USE

Accessories and Device Challenges by STERRAD Sterilization Modalities for all Perforated Bottom Containers

Contents/Configuration	STERRAD NX Standard	STERRAD NX Advanced	STERRAD 100NX Standard	STERRAD 100NX Flex	STERRAD 100NX Express
Baskets	Yes	Yes	Yes	Yes	Yes
Stacking Baskets	Yes	Yes	Yes	No	Yes
Lumen: 0.7 mm (ID) x 500 mm (L) Stainless Steel	No	No	Yes, max 10	No	No
Lumen: 1.0 mm (ID) x 150 mm (L) Stainless Steel	Yes, max 10	Yes, max 10	Yes, max 10	No	No
Lumen: 2.0 mm (ID) x 400mm (L) Stainless Steel	Yes, max 10	Yes, max 10	Yes, max 10	No	No
Lumen: 1.0 mm (ID) x 500 mm (L) Stainless Steel	No	Yes, max 10	Yes, max 10	No	No
Lumen 1.0 mm (ID) x 850 mm (L) PE/PTFE	No	Yes, max 1	No	Yes, max 2	No
Occluded/Mated challenge	Yes	Yes	Yes	No	Yes
Silicone Support Bars	Yes	Yes	Yes	Yes	Yes
Silicone Mat	No	No	No	No	No
Filter	DST series	DST series	DST series	DST series	DST series
Data Cards	MH1-1	MH1-1	MH1-1	MH1-1	MH1-1
Tamper Evident Arrow	Pink AH Series	Pink AH Series	Pink AH Series	Pink AH Series	Pink AH Series
Stack Height	No stacking	No stacking	No stacking	No stacking	No stacking
Materials	Compatible with materials cleared for STERRAD NX	Compatible with materials cleared for STERRAD NX	Compatible with materials cleared for STERRAD 100NX	Compatible with materials cleared for STERRAD 100NX	Compatible with materials cleared for STERRAD 100NX
Maximum Total Weight	10.7 lbs.	Lumen load: 10.7 lbs.; Endoscope load: no additional load	21.4 lbs.	No additional load	10.7 lbs.

K153554 INDICATIONS FOR USE

Accessories and Device Challenges by V-PRO 1 / 1 Plus / maX Sterilization Modalities for all Perforated Bottom Containers

Contents/Configuration	V-PRO 1 Plus, maX Non-Lumen	V-PRO 1, 1 Plus, maX Lumen	V-PRO maX Flexible
Baskets	Yes	Yes	Yes
Stacking Baskets	Yes	Yes	No
Single Channel 0.77mm (ID) x 500 mm (L) Stainless Steel; Dual Channel 0.77 mm (ID) x 527 mm (L) Stainless Steel; Triple Channel 1.2 mm (ID) x 275 mm (L), 1.8 mm (ID) x 310 mm (L), 2.8 mm (ID) x 317 mm (L) Stainless Steel	No	Yes, max 20	No
Flexible Endoscopes: Single Lumen 1.0 mm (ID) x 1050 mm (L) OR Two lumens • 1.0 mm (ID) x 998 mm (L) • 1.0 mm (ID) x 850 mm (L)	No	No	Yes QTY. 2 (with no additional load) QTY 1 (with instruments for 24 lbs total load)
Occluded/Mated challenge	Yes	Yes	Yes
Silicone Support Bars	Yes	Yes	Yes
Silicone Mat	Yes	Yes	Yes
Filter	DST Series	DST Series	DST Series
Data Cards	MH1-1	MH1-1	MH1-1
Tamper Evident Arrow	Pink AH Series	Pink AH Series	Pink AH Series
Stack Height	No stacking	No stacking	No stacking
Materials	Compatible with materials cleared for V-PRO	Compatible with materials cleared for V-PRO	Compatible with materials cleared for V-PRO
Maximum Total Weight	19.65 lbs.	19.65 lbs.	2 scopes, or one scope plus instruments for total of 24 lbs.

K153554 INDICATIONS FOR USE

Accessories and Device Challenges by V-PRO 60 Sterilization Modalities for all Perforated Bottom Containers

Contents/Configuration	V-PRO 60 Non-Lumen	V-PRO 60 Lumen	V-PRO 60 Flexible
Baskets	Yes	Yes	Yes
Stacking Baskets	Yes	Yes	No
Single Channel 0.77mm (ID) x 410 mm (L) Stainless Steel; Dual Channel 0.77 mm (ID) x 410 mm (L) Stainless Steel; Triple Channel 1.2 mm (ID) x 275 mm (L), 1.8 mm (ID) x 310 mm (L), 2.8 mm (ID) x 317 mm (L) Stainless Steel	No	Yes, max 12	No
Flexible Endoscopes: Single Lumen 1.0 mm (ID) x 990 mm (L) OR Two lumens 1.0 mm (ID) x 990 mm (L)	No	No	Yes QTY. 1 (with no additional load)
Occluded/Mated challenge	Yes	Yes	Yes
Silicone Support Bars	Yes	Yes	Yes
Silicone Mat	Yes	Yes	Yes
Filter	DST Series	DST Series	DST Series
Data Cards	MH1-1	MH1-1	MH1-1
Tamper Evident Arrow	Pink AH Series	Pink AH Series	Pink AH Series
Stack Height	No stacking	No stacking	No stacking
Materials	Compatible with materials cleared for V-PRO 60	Compatible with materials cleared for V-PRO 60	Compatible with materials cleared for V-PRO 60
Maximum Total Weight	12.0 lbs.	11.0 lbs.	No additional load

K153554 INDICATIONS FOR USE

Perforated Bottom Containers

Catalog Code	Description	Container Dimension (in)	Container Weight (lbs.)
CD0-3LT	Mini – Perforated Bottom	10.2 x 7.2 x 3.2	2.6
CD0-4LT	Quarter Length – Perforated Bottom	9.5 x 12.4 x 3.8	3.7
DINCD1-5LT	Half-Length – Perforated Bottom	11.6 x 11.4 x 5.4	4.8
DINCD1-6LT	Half-Length – Perforated Bottom	11.6 x 11.4 x 6.1	5.0
DINCD2-5LT	Mid-Length – Perforated Bottom	19.2 x 11.4 x 5.4	6.5
DINCD2-6LT	Mid-Length – Perforated Bottom	19.2 x 11.4 x 6.1	6.7
DINCD2-8LT	Mid-Length – Perforated Bottom	19.2 x 11.4 x 7.8	7.2
DINCD3-5LT	Full-Length – Perforated Bottom	23.1 x 11.4 x 5.4	7.6
DINCD3-6LT	Full-Length – Perforated Bottom	23.1 x 11.4 x 6.1	7.9
DINCD3-7LT	Full-Length – Perforated Bottom	23.1 x 11.4 x 7.1	8.2
CD4-3LT	Small Narrow – Perforated Bottom	20.8 x 7.3 x 3.9	4.2
CD4-5LT	Small Narrow – Perforated Bottom	20.8 x 7.3 x 5.2	4.8

510(k) SUMMARY: K153554

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

I. SUBMITTER INFORMATION	
Name	CareFusion 2200 Inc
Address	75 N. Fairway Dr. Vernon Hills, IL 60061
Phone number	(847) 362-8094
Fax number	(312) 949-0272
Establishment Registration Number	1423507
Name of contact person	Jane Weber, Regulatory Affairs Manager
Date prepared	18-MAR-2016
II. DEVICE INFORMATION	
Name of Device	Genesis™ Low Temperature Reusable Rigid Container System
Common or usual name	Sterilization Container
Classification name	Sterilization Wrap, Containers, Trays, Cassettes and Other Accessories
Regulatory Class	Class II per 21CFR 880.6850, Product code KCT
Product Code	KCT
III. PREDICATE DEVICE	
Genesis™ Rigid Reusable Sterilization Container System, K142529 This predicate has not been subject to a design-related recall. No reference devices were used in this submission.	
IV. DEVICE DESCRIPTION	
The Genesis™ Low Temperature Container System is an assortment of rigid, reusable, stackable containers that are used to enclose other medical devices and maintain sterility of these devices until used. The container system is comprised of a lid, bottom, filter, tamper evident arrows, and data cards. The container system houses baskets of varying depths and organizing accessory devices that are used to organize and to secure surgical instrumentation and/or other medical devices.	
V. INDICATIONS FOR USE	
The Genesis™ Low Temperature Sterilization Container System is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It allows sterilization of the enclosed medical device and maintains sterility of the enclosed medical device until used for a maximum of 180 days. Containers are suitable for various STERRAD and V-PRO low temperature sterilization modalities when used as described in the instructions for use. Reusable baskets and accessory items (pins, dividers, mats, etc.) are intended to organize and secure enclosed medical devices during sterilization and storage of the container. Data cards are used to record information regarding a specific sterilization process load. Filter media allows ingress and egress of sterilant while providing a microbial barrier. Tamper evident arrows provide a visual indication that the container system has not been inadvertently opened prior to use. Each arrow	

contains a modality-specific external process indicator that serves as a visual indication that the system has been exposed to a specific sterilization cycle parameter. Data cards, filters and tamper evident arrows are single use only.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Characteristic	Predicate Device - K142529	New/Modified Device
Intended Use	A sterilization container system is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed medical device until used.	Same
Container	Anodized aluminum 5000 and 1100 series; stainless steel 300 series	Same
Gasket	Closed cell silicone foam	Same
Filter	SMS polypropylene for all sterilization modalities	Same
Baskets	304 Stainless Steel, electropolished	Same
Dividers, brackets	Aluminum 5000 series	Same
Clips, posts, pins	Stainless Steel 300 and 400 series	Same
Silicone bars, mats	Silicone Elastomer	Same
Volume to Vent Ratio	24.0 to 182.3 in^3 / in^2	29.3 to 87.3 in^3/in^2
Sterilization Modalities	Pre-Vacuum Steam 100% Ethylene Oxide	STERRAD® NX Standard STERRAD® NX Advanced STERRAD® 100NX Standard STERRAD® 100NX Flex STERRAD® 100NX Express V-PRO 1 Lumen V-PRO 1 Plus Lumen V-PRO 1 Plus Non-Lumen V-PRO maX Lumen V-PRO maX Non-Lumen V-PRO maX Flexible V-PRO 60 Lumen V-PRO 60 Non-Lumen V-PRO 60 Flexible

VII. PERFORMANCE DATA – NON CLINICAL

The following non-clinical performance tests were provided in support of the substantial equivalence determination.

Characteristic	Standard / Test / FDA Guidance	Results Summary
Sterilization Efficacy - Lethality STERRAD NX (Standard, Advanced) STERRAD 100 NX (Standard, Flex, Express) V-PRO (Non-Lumen, Lumen, Flexible)	ANSI AAMI ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	Testing demonstrated a 12 log reduction and a sterility assurance level (SAL) of 10^{-6} using biological (BI) overkill method
Aerosol Challenge STERRAD NX Advanced STERRAD 100NX Standard VPRO 60 Lumen	ANSI AAMI ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	Containers subjected to an aerosol challenge test with an exposure of 1.0 - 5.0 x 10^6 CFU. Agar vessels placed in each container sample demonstrated no growth of the indicator organism following the incubation period
Cycled Aerosol / Limits of Reuse STERRAD 100NX Standard VPRO 1-Plus/60 Lumen	ANSI AAMI ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	After 100 simulated full use cycles or the equivalent followed by an aerosol challenge test with an exposure of 1.0 - 5.0 x 10^6 CFU. Agar vessels placed in each container sample demonstrated no growth of the indicator organism following the incubation period
Simulated Use STERRAD NX Advanced STERRAD 100NX Flex VPRO maX Flexible VPRO 60 Flexible	ANSI AAMI ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	Testing demonstrated no recovery of viable challenge organism (all sterile results) from the lumens on the test device after processing within a worst case Genesis Container as part of a worst case cycle simulated use container validation load
Shelf Life / Package Integrity STERRAD NX Advanced STERRAD 100NX Standard VPRO 60 Lumen	ANSI AAMI ST 77 2013 Containment Devices for Reusable Medical Device Sterilization	All sample devices remained sterile (exhibit no growth) following exposure to a full sterilization cycle and weekly rotation events at a 180 day storage duration
Filter Material Properties STERRAD NX Advanced STERRAD 100NX Standard VPRO 60 Lumen	Filter properties (Bacterial Filtration Efficiency, Trapezoidal Tear Strength, and Burst Strength) prior to and after exposure to a full sterilization cycle were reported	All filter properties were found to be acceptable
Biocompatibility STERRAD NX Advanced STERRAD 100NX Standard VPRO 60 Lumen	ISO 10993-4 2009	Blood hemolysis testing demonstrated that any accessories used in the Genesis™ Low Temperature Sterilization Container System are acceptable for use after processing in the low temperature sterilization modalities

VIII. PERFORMANCE DATA - CLINICAL

There was no clinical testing performed in support of the substantial equivalence determination.

IX. CONCLUSIONS DRAWN FROM NON-CLINCAL DATA

The Genesis™ Low Temperature Container System has been validated to meet the established performance criteria. The device is substantially equivalent to the predicate device.

510(k) SUMMARY: K153554

Sterilization Cycle Parameters for the Genesis Low Temperature Reusable Rigid Container System by Modality

Sterilization Cycle Parameters	Load Configuration	
	Total System Weight	**Applicable Containers / Accessories**
STERRAD NX Standard Push button cycle with non-adjustable parameters	10.7 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Lumen Devices (1.0 mm x 150 mm) Stainless Steel, Qty. 10 Lumen Devices (2.0 mm x 400 mm) Stainless Steel, Qty. 10 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD NX
STERRAD NX Advanced Push button cycle with non-adjustable parameters	10.7 lbs. (Endoscope load: no additional load)	Perforated Bottom Low Temperature Containers; Stacking Baskets Lumen Devices (1.0 mm x 150 mm) Stainless Steel, Qty. 10 Lumen Devices (2.0 mm x 400 mm) Stainless Steel, Qty. 10 Lumen Devices (1.0 mm x 500 mm) Stainless Steel, Qty. 10 Lumen Devices (1.0 mm x 850 mm) PE/PTFE, Qty. 1 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD NX
STERRAD 100NX Standard Push button cycle with non-adjustable parameters	21.4 lbs.	Perforated Bottom Low Temperature Containers; Stacking baskets Lumen Devices (0.7 mm x 500 mm) Stainless Steel, Qty. 10 Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD 100NX
STERRAD 100NX Flex Push button cycle with non-adjustable parameters	No additional load	Perforated Bottom Low Temperature Containers; Lumen Devices (1.0 mm x 850 mm) PE/PTFE, Qty. 2 Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD 100NX
STERRAD 100NX Express Push button cycle with non-adjustable parameters	10.7 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars *Materials: Compatible with materials cleared for STERRAD 100NX

510(k) SUMMARY: K153554

Sterilization Cycle Parameters	Load Configuration	
	Total System Weight	**Applicable Containers / Accessories**
V-PRO 1 Plus maX Non-Lumen Push button cycle with non-adjustable parameters	19.65 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO
V-PRO 1, 1 Plus maX Lumen Push button cycle with non-adjustable parameters	19.65 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Single Channel (0.77 mm x 500mm) Stainless Steel; Dual channel (0.77 mm x 527mm) Stainless Steel; Triple Channel (1.2 mm x 275 mm, 1.8 mm x 310 mm, 2.8 mm x 317 mm) Stainless Steel; Max 20 lumens per load Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO
V-PRO maX Flexible Push button cycle with non-adjustable parameters	2 scopes, or One scope + instruments for total of 24.0 lbs.	Perforated Bottom Low Temperature Containers; Flexible Endoscopes – Qty. 2 w/ no additional load; Qty. 1 w/ instrument load for 24 lbs total Single Lumen (1 mm x 1050mm) or Two lumens, one (1 mm x 998 mm) the other (1 mm x 850 mm) Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO
V-PRO 60 Non-Lumen Push button cycle with non-adjustable parameters	12.0 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO 60

510(k) SUMMARY: K153554

Sterilization Cycle Parameters	Load Configuration	
	Total System Weight	**Applicable Containers / Accessories**
V-PRO 60 Lumen Push button cycle with non-adjustable parameters	11.0 lbs.	Perforated Bottom Low Temperature Containers; Stacking Baskets Single Channel (0.77 mm x 410 mm) Stainless Steel; Dual Channel (0.77 mm x 410 mm) Stainless Steel; Triple Channel (1.2 mm x 275 mm, 1.8 mm x 310 mm, 2.8 mm x 317 mm) Stainless Steel; Max 12 lumens per load Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO 60
V-PRO 60 Flexible Push button cycle with non-adjustable parameters	No additional load	Perforated Bottom Low Temperature Containers; Flexible Endoscopes, Qty. 1 Single Lumen (1.0 mm x 990 mm) or Two Lumens (1.0 mm x 990 mm) Devices or Device Configurations entailing conjoined surfaces which meet, touch or unite; Silicone Support Bars Silicone Mats *Materials: Compatible with materials cleared for V-PRO 60
Examples of instrument types that are conjoined include: a lumen secured to a silicone bar, an instrument placed on a silicone mat, a double action instrument with mated parts held open. Note: Air tight occluded challenges - devices with surfaces that are completely obstructed - have **not** been validated for use in the Genesis Low Temperature Reusable Sterilization Container System. *Materials: For examples of materials supported in the STERRAD NX, STERRAD 100NX, V-PRO 1, V-PRO 1 Plus, V-PRO maX, and V-PRO 60 sterilization modalities, please refer to the corresponding Instructions for Use from the sterilizer manufacturer.		

Accessories and Device Challenges by STERRAD Sterilization Modalities for all Perforated Bottom Containers

Contents/Configuration	STERRAD NX Standard	STERRAD NX Advanced	STERRAD 100NX Standard	STERRAD 100NX Flex	STERRAD 100NX Express
Baskets	Yes	Yes	Yes	Yes	Yes
Stacking Baskets	Yes	Yes	Yes	No	Yes
Lumen: 0.7 mm (ID) x 500 mm (L) Stainless Steel	No	No	Yes, max 10	No	No
Lumen: 1.0 mm (ID) x 150 mm (L) Stainless Steel	Yes, max 10	Yes, max 10	Yes, max 10	No	No
Lumen: 2.0 mm (ID) x 400mm (L) Stainless Steel	Yes, max 10	Yes, max 10	Yes, max 10	No	No
Lumen: 1.0 mm (ID) x 500 mm (L) Stainless Steel	No	Yes, max 10	Yes, max 10	No	No
Lumen 1.0 mm (ID) x 850 mm (L) PE/PTFE	No	Yes, max 1	No	Yes, max 2	No
Occluded/Mated challenge	Yes	Yes	Yes	No	Yes
Silicone Support Bars	Yes	Yes	Yes	Yes	Yes
Silicone Mat	No	No	No	No	No
Filter	DST series	DST series	DST series	DST series	DST series
Data Cards	MH1-1	MH1-1	MH1-1	MH1-1	MH1-1
Tamper Evident Arrow	Pink AH Series	Pink AH Series	Pink AH Series	Pink AH Series	Pink AH Series
Stack Height	No stacking	No stacking	No stacking	No stacking	No stacking
Materials	Compatible with materials cleared for STERRAD NX	Compatible with materials cleared for STERRAD NX	Compatible with materials cleared for STERRAD 100NX	Compatible with materials cleared for STERRAD 100NX	Compatible with materials cleared for STERRAD 100NX
Maximum Total Weight	10.7 lbs.	Lumen load: 10.7 lbs.; Endoscope load: no additional load	21.4 lbs.	No additional load	10.7 lbs.

Accessories and Device Challenges by V-PRO 1 / 1 Plus / maX Sterilization Modalities for all Perforated Bottom Containers

Contents/Configuration	V-PRO 1 Plus, maX Non-Lumen	V-PRO 1, 1 Plus, maX Lumen	V-PRO maX Flexible
Baskets	Yes	Yes	Yes
Stacking Baskets	Yes	Yes	No
Single Channel 0.77mm (ID) x 500 mm (L) Stainless Steel; Dual Channel 0.77 mm (ID) x 527 mm (L) Stainless Steel; Triple Channel 1.2 mm (ID) x 275 mm (L), 1.8 mm (ID) x 310 mm (L), 2.8 mm (ID) x 317 mm (L) Stainless Steel	No	Yes, max 20	No
Flexible Endoscopes: Single Lumen 1.0 mm (ID) x 1050 mm (L) OR Two lumens • 1.0 mm (ID) x 998 mm (L) • 1.0 mm (ID) x 850 mm (L)	No	No	Yes QTY. 2 (with no additional load) QTY 1 (with instruments for 24 lbs total load)
Occluded/Mated challenge	Yes	Yes	Yes
Silicone Support Bars	Yes	Yes	Yes
Silicone Mat	Yes	Yes	Yes
Filter	DST Series	DST Series	DST Series
Data Cards	MH1-1	MH1-1	MH1-1
Tamper Evident Arrow	Pink AH Series	Pink AH Series	Pink AH Series
Stack Height	No stacking	No stacking	No stacking
Materials	Compatible with materials cleared for V-PRO	Compatible with materials cleared for V-PRO	Compatible with materials cleared for V-PRO
Maximum Total Weight	19.65 lbs.	19.65 lbs.	2 scopes, or one scope plus instruments for total of 24 lbs.

Accessories and Device Challenges by V-PRO 60 Sterilization Modalities for all Perforated Bottom Containers

Contents/Configuration	V-PRO 60 Non-Lumen	V-PRO 60 Lumen	V-PRO 60 Flexible
Baskets	Yes	Yes	Yes
Stacking Baskets	Yes	Yes	No
Single Channel 0.77mm (ID) x 410 mm (L) Stainless Steel; Dual Channel 0.77 mm (ID) x 410 mm (L) Stainless Steel; Triple Channel 1.2 mm (ID) x 275 mm (L), 1.8 mm (ID) x 310 mm (L), 2.8 mm (ID) x 317 mm (L) Stainless Steel	No	Yes, max 12	No
Flexible Endoscopes: Single Lumen 1.0 mm (ID) x 990 mm (L) OR Two lumens 1.0 mm (ID) x 990 mm (L)	No	No	Yes QTY. 1 (with no additional load)
Occluded/Mated challenge	Yes	Yes	Yes
Silicone Support Bars	Yes	Yes	Yes
Silicone Mat	Yes	Yes	Yes
Filter	DST Series	DST Series	DST Series
Data Cards	MH1-1	MH1-1	MH1-1
Tamper Evident Arrow	Pink AH Series	Pink AH Series	Pink AH Series
Stack Height	No stacking	No stacking	No stacking
Materials	Compatible with materials cleared for V-PRO 60	Compatible with materials cleared for V-PRO 60	Compatible with materials cleared for V-PRO 60
Maximum Total Weight	12.0 lbs.	11.0 lbs.	No additional load

K153554 510(k) SUMMARY

Perforated Bottom Containers

Catalog Code	Description	Container Dimension (in)	Container Weight (lbs.)
CD0-3LT	Mini – Perforated Bottom	10.2 x 7.2 x 3.2	2.6
CD0-4LT	Quarter Length – Perforated Bottom	9.5 x 12.4 x 3.8	3.7
DINCD1-5LT	Half-Length – Perforated Bottom	11.6 x 11.4 x 5.4	4.8
DINCD1-6LT	Half-Length – Perforated Bottom	11.6 x 11.4 x 6.1	5.0
DINCD2-5LT	Mid-Length – Perforated Bottom	19.2 x 11.4 x 5.4	6.5
DINCD2-6LT	Mid-Length – Perforated Bottom	19.2 x 11.4 x 6.1	6.7
DINCD2-8LT	Mid-Length – Perforated Bottom	19.2 x 11.4 x 7.8	7.2
DINCD3-5LT	Full-Length – Perforated Bottom	23.1 x 11.4 x 5.4	7.6
DINCD3-6LT	Full-Length – Perforated Bottom	23.1 x 11.4 x 6.1	7.9
DINCD3-7LT	Full-Length – Perforated Bottom	23.1 x 11.4 x 7.1	8.2
CD4-3LT	Small Narrow – Perforated Bottom	20.8 x 7.3 x 3.9	4.2
CD4-5LT	Small Narrow – Perforated Bottom	20.8 x 7.3 x 5.2	4.8