July 5, 2024

Advanced Sterilization Products
Ayse Erkan
Sr. Regulatory Affairs Program Lead
33 Technology Dr.
Irvine, California 92618

Re: K234082
Trade/Device Name: STERRAD® 100NX Sterilizer with ALLClear™ Technology (10104); APTIMAX™ Instrument Tray for ULTRA GI™ Cycle (011077)
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene oxide gas sterilizer
Regulatory Class: Class II
Product Code: MLR, FRG
Dated: December 22, 2023
Received: June 7, 2024

Dear Ayse Erkan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Christopher K. Dugard -S

Christopher K. Dugard, M.S.
Assistant Director
DHT4B: Division of Infection Control

and Plastic and Reconstructive Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234082

Device Name
STERRAD™ 100NX Sterilizer with ALLClear™ Technology and ULTRA GI™ Cycle (10104)
APTIMAX™ Instrument Tray for ULTRA GI Cycle (011077)

Indications for Use *(Describe)*

The STERRAD 100NX Sterilizer with ALLClear Technology is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The STERRAD sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to safely sterilize medical instruments and materials without leaving toxic residue.

The STERRAD 100NX Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Medical devices with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer STANDARD cycle:

• Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter. A maximum of ten single channel stainless steel lumens, five per tray per sterilization cycle.

Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer FLEX Scope cycle:

• Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of 1065 mm or shorter. A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load.

Note: With the exception of the 1 x 1065 mm flexible endoscopes, the validation studies were performed using a validation load consisting of two instrument trays each weighing 10.7 lbs. The 1 x 1065 mm flexible endoscopes were validated without any additional load.

The STERRAD 100NX EXPRESS Cycle is an additional optional cycle designed for surface sterilization of both metal and nonmetal medical devices at low temperatures.

• It can sterilize instrument surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors

• It can sterilize rigid and semi-rigid endoscopes without lumens.

Note: The validation studies for EXPRESS Cycle were performed using a validation load consisting of a single instrument tray weighing 10.7 lbs placed on the bottom shelf.

The STERRAD 100NX DUO Cycle is an additional optional cycle designed for sterilization of medical devices including most flexible endoscopes, with the following materials and dimensions:

• Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and a length of 875 mm or shorter

• Accessory devices that are normally connected to a flexible endoscope during use

• Flexible endoscopes without lumens

Note: The validation studies for DUO Cycle were performed using a validation load consisting of two flexible endoscopes with their accessory devices weighing a total of 13.2 lbs.

The STERRAD 100NX Sterilizer ULTRA GI Cycle is designed for sterilization of the following:

• Hydrogen peroxide compatible flexible multi-channel duodenoscopes, with no more than 4 channels, with lumen dimensions having an inside diameter (ID) of ≥1mm x ≤1500mm in length, or ≥2mm ID x ≤1630mm in length.

• One flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle

Note1: The STERRAD 100NX Sterilizer ULTRA GI Cycle was validated using a load weight of 15.4 lbs (2 x 7.7 lbs), one endoscope per shelf. Note 2: Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD User Guide "STERRAD Sterilizer Cycle Selection table" for ULTRA GI Cycle compatible duodenoscopes.

The APTIMAX™ Tray for ULTRA GI™ Cycle is designed to encase surgical instruments for sterilization in

STERRAD™ 100NX Sterilization System with ALLCLEAR™ Technology:
• ULTRA GI™ Cycle

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)

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510(k) Summary for K234082
Advanced Sterilization Products, Inc.
STERRAD™ 100NX Sterilizer with ALLClear™ Technology and ULTRA GI™ Cycle
APTIMAX™ Instrument Tray for ULTRA GI Cycle

This summary of 510(k) Safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Submitter Name: Advanced Sterilization Products, Inc.

Address: 33 Technology Drive
Irvine, CA 92618

Contact Person: Ayse Erkan
Senior Regulatory Affairs Program Lead
Telephone: (714)580-2880
Email: ayse.erkan@asp.com

Date Prepared: July 1, 2024

Devices Names

Proprietary Name:	**STERRAD™ 100NX Sterilizer with ALLClear™ Technology and ULTRA GI™ Cycle (10104)**	**APTIMAX™ Instrument Tray for ULTRA GI Cycle (011077)**
Device Common Name:	Hydrogen Peroxide Gas Plasma Sterilization System	Sterilizable Instrument Tray and Accessories
Classification Name:	Ethylene Oxide Gas Sterilizer	Wrap, sterilization
Product Code:	MLR	FRG
Device Class:	Class II	Class II
CFR Section:	21 CFR 880.6860	21 CFR 880.6850

Predicate Devices

STERRAD 100NX Sterilizer with ALLClear Technology K212174 cleared October 9, 2021
APTIMAX Instrument Tray K013003 cleared August 28, 2002.

Reference Device

EOGas 4 Ethylene Oxide Gas Sterilizer K192978 cleared November 12, 2020.

Device Description

The STERRAD 100NX Sterilization System with ALLClear Technology is a self-contained stand-alone system of hardware and software designed to sterilize medical instruments and devices using a patented hydrogen peroxide gas plasma process. Hydrogen peroxide vapor is generated by injecting aqueous hydrogen peroxide into the vaporizer where the solution is heated and vaporized, introducing the vapor into the chamber under sub-ambient pressure and transforming the vapor into a gas plasma using electrical energy. The sterilization process is a multiphase process that utilizes a combination of

exposure to hydrogen peroxide vapor and plasma to achieve sterilization. The hardware for the STERRAD 100NX Sterilizer consists of a sterilizer chamber and a variety of instruments and components which are housed in a covered frame. The sterilizer also uses accessories such as reusable instrument trays, biological indicator, chemical indicator products and sterilant cassettes. The STERRAD 100NX Sterilizer has four cleared sterilization cycles: STANDARD, FLEX, EXPRESS, and DUO Cycles.

The STERRAD 100NX Sterilizer described within this submission introduces the new ULTRA GI Cycle along with the new APTIMAX Instrument Tray for ULTRA GI Cycle.

The STERRAD 100NX Sterilizer ULTRA GI Cycle is an additional optional cycle designed for sterilization of the following:

- Hydrogen peroxide compatible flexible multi-channel duodenoscopes, with no more than 4 channels, with lumen dimensions having an inside diameter (ID) of ≥1mm x ≤1500mm in length, or ≥2mm ID x ≤1630mm in length.
- One flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle

Note 1: The STERRAD 100NX Sterilizer ULTRA GI Cycle was validated using a load weight of 15.4 lbs (2 x 7.7 lbs), one endoscope per shelf.

Note 2: Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD Sterilizer Cycle Selection table for ULTRA GI Cycle compatible duodenoscopes.

The APTIMAX Instrument Tray for ULTRA GI Cycle is designed to encase surgical instruments for sterilization in STERRAD 100NX Sterilization System with ALLClear Technology:

- ULTRA GI Cycle

This cycle is designed to run on STERRAD 100NX System with ALLClear Technology with the DUO Module enabled. ALLClear Technology features of Load Check, System Check, and Load Conditioning are integrated into the ULTRA GI cycle.

Intended Use/Indications for Use

The intended use of the subject STERRAD 100NX Sterilizer with ALLClear Technology has not changed with the proposed expanded indications for use in the ULTRA GI Cycle. The APTIMAX Tray for ULTRA GI Cycle is designed to encase surgical instruments for sterilization in STERRAD 100NX Sterilization System with ALLCLEAR Technology. Refer to Table 1, Comparison between the subject device and predicate devices and Table 2, APTIMAX ULTRA GI Instrument Tray Predicate Device Comparison for of Intended Use & Indications for Use Comparison.

Technological Characteristics

The technological characteristics associated with the sterilization process of the proposed STERRAD 100NX Sterilizer with ALLClear Technology with expanded indications for the ULTRA GI Cycle in combination with the APTIMAX Tray for ULTRA GI Cycle is designed to run on STERRAD 100NX System with ALLClear Technology with the DUO Module enabled. ALLClear Technology features of Load Check, System Check, and Load Conditioning are integrated into the ULTRA GI cycle.

The subject devices continue to have the same technological characteristics, sterilization, performance, and physical traits as the predicate devices, STERRAD 100NX Sterilizer with ALL Clear Technology and the APTIMAX Instrument Tray.

Table 1. Comparison between the subject device and predicate devices

Feature	STERRAD 100NX Sterilizer with ALLClear Technology with ULTRA GI Cycle Subject Device	STERRAD 100NX Sterilizer with ALLClear Technology K212174 Predicate Device	Comparison
Intended Use	Designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.	Designed for sterilization of both metal and nonmetal medical devices at low temperatures. Because the cycle operates within a dry environment and at low temperatures, it is especially suitable for instruments sensitive to heat and moisture.	Identical
Indications for Use	The STERRAD 100NX Sterilizer with ALLClear Technology is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The STERRAD sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to safely sterilize medical instruments and materials without leaving toxic residue. The STERRAD 100NX Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer STANDARD cycle: • Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter. A maximum of ten single channel stainless steel lumens, five per tray per sterilization cycle. Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer FLEX Scope cycle: • Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of 1065 mm or shorter. A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load. Note: With the exception of the 1 x 1065 mm flexible endoscopes, the validation studies were performed using a validation load consisting of two instrument trays each weighing 10.7 lbs. The 1 x 1065 mm	The STERRAD 100NX Sterilizer with ALLClear Technology is designed for sterilization of both metal and nonmetal medical devices at low temperatures. The STERRAD sterilization process is a multiphase sterilization process that utilizes a combination of exposure to hydrogen peroxide vapor and plasma to safely sterilize medical instruments and materials without leaving toxic residue. The STERRAD 100NX Sterilizer can sterilize instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer STANDARD cycle: • Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter. A maximum of ten single channel stainless steel lumens, five per tray per sterilization cycle. Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer FLEX Scope cycle: • Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of 1065 mm or shorter. A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load. Note: With the exception of the 1 x 1065 mm flexible endoscopes, the validation studies were performed using a validation load consisting of two instrument trays each weighing 10.7 lbs. The 1 x 1065 mm	Similar, includes additional indications for Use for ULTRA GI cycle.

Feature	STERRAD 100NX Sterilizer with ALLClear Technology with ULTRA GI Cycle Subject Device	STERRAD 100NX Sterilizer with ALLClear Technology K212174 Predicate Device	Comparison
	flexible endoscopes were validated without any additional load. The STERRAD 100NX EXPRESS Cycle is an additional optional cycle designed for surface sterilization of both metal and nonmetal medical devices at low temperatures. • It can sterilize instrument surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors • It can sterilize rigid and semi-rigid endoscopes without lumens. Note: The validation studies for EXPRESS Cycle were performed using a validation load consisting of a single instrument tray weighing 10.7 lbs placed on the bottom shelf. The STERRAD 100NX DUO Cycle is an additional optional cycle designed for sterilization of medical devices including most flexible endoscopes, with the following materials and dimensions: • Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and a length of 875 mm or shorter • Accessory devices that are normally connected to a flexible endoscope during use • Flexible endoscopes without lumens Note: The validation studies for DUO Cycle were performed using a validation load consisting of two flexible endoscopes with their accessory devices weighing a total of 13.2 lbs. The STERRAD 100NX Sterilizer ULTRA GI Cycle is designed for sterilization of the following: • Hydrogen peroxide compatible flexible multi-channel duodenoscopes, with no more than 4 channels, with lumen dimensions having an inside diameter (ID) of ≥1mm x ≤1500mm in length, or ≥2mm ID x ≤1630mm in length.	flexible endoscopes were validated without any additional load. The STERRAD 100NX EXPRESS Cycle is an additional optional cycle designed for surface sterilization of both metal and nonmetal medical devices at low temperatures. • It can sterilize instrument surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors • It can sterilize rigid and semi-rigid endoscopes without lumens. Note: The validation studies for EXPRESS Cycle were performed using a validation load consisting of a single instrument tray weighing 10.7 lbs placed on the bottom shelf. The STERRAD 100NX DUO Cycle is an additional optional cycle designed for sterilization of medical devices including most flexible endoscopes, with the following materials and dimensions: • Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and a length of 875 mm or shorter • Accessory devices that are normally connected to a flexible endoscope during use • Flexible endoscopes without lumens Note: The validation studies for DUO Cycle were performed using a validation load consisting of two flexible endoscopes with their accessory devices weighing a total of 13.2 lbs.	

Feature	STERRAD 100NX Sterilizer with ALLClear Technology with ULTRA GI Cycle Subject Device	STERRAD 100NX Sterilizer with ALLClear Technology K212174 Predicate Device	Comparison
	• One flexible duodenoscope per tray, and no more than two flexible duodenoscope per cycle Note 1: The STERRAD 100NX Sterilizer ULTRA GI Cycle was validated using a load weight of 15.4 lbs (2 x 7.7 lbs), one endoscope per shelf. Note 2: Only duodenoscopes that have been cleared as compatible with vaporized hydrogen peroxide are acceptable. Check STERRAD Sterilizer Cycle Selection table for ULTRA GI Cycle compatible duodenoscopes		
Sterilization Cycles	ULTRA GI STANDARD FLEX EXPRESS DUO	STANDARD FLEX EXPRESS DUO	Identical
Dimensions	One Door: 30.5" W x 70.9" H x 41.5" D (775 mm x 1800 mm x 1055 mm) Two Door: 30.5" W x 70.9" H x 43.1" D (775 mm x 1800 mm x 1095 mm)	One Door: 30.5" W x 70.9" H x 41.5" D (775 mm x 1800 mm x 1055 mm) Two Door: 30.5" W x 70.9" H x 43.1" D (775 mm x 1800 mm x 1095 mm)	Identical
H_2O_2 Concentration by Weight	59-94% Depending on Cycle	59-94% Depending on Cycle	Identical
Number Of Half Cycles	2	2	Identical
Chamber Volume	152L	152L	Identical
Key Critical Process Parameters	Pressure, temperature & H2O2 concentration, H2O2 Dose & Exposure Time	Pressure, temperature & H2O2 concentration, H2O2 Dose & Exposure Time	Identical
Use of Pre-Conditioning Step	Yes	Yes	Identical
Use of Secondary Step to Remove Residual H2O2 (technology)	Yes (plasma)	Yes(plasma)	Identical

Table 2. APTIMAX ULTRA GI Instrument Tray Predicate Device Comparison

Feature	APTIMAX ULTRA GI Instrument Tray Subject Device	APTIMAX Instrument Tray K013003 Predicate Device	Comparison
Indications for Use	Designed to encase instruments for sterilization	Designed to encase instruments for sterilization	Identical

Feature	APTIMAX ULTRA GI Instrument Tray Subject Device	APTIMAX Instrument Tray K013003 Predicate Device	Comparison
Reusable/Single Use	Reusable	Reusable	Identical
Classification Name	Sterilization Wrap	Sterilization Wrap	Identical
Classification Regulation	21 CFR 880.6850	21 CFR 880.6850	Identical
Product Code	FRG	FRG	Identical
Class	II	II	Identical
Panel	General Hospital	General Hospital	Identical
Method of Sterilization	For use in only the STERRAD 100NX ULTRA GI Cycle	For use in STERRAD System, steam and Ethylene Oxide sterilization cycles	Similar, subject device is designed to be used with ULTRA GI cycle
Materials of Construction	Tray & Lid: 5052 Aluminum Latch: 304 Stainless Steel	Hoechst Celanese's Vectral A130 Liquid Crystal Polymer	Similar, both were manufactured from medical grade materials
STERRAD 100NX Sterilization Cycles	Only to be used for the STERRAD 100NX ULTRA GI Cycle	STANDARD, FLEX, EXPRESS and DUO	Similar, subject device is designed to be used with ULTRA GI cycle
Dimensions	12.6" W x 19.4" L x 4.3" H	3-10" W x 7-23.6" L x 1-2" H	Similar, dimensions designed to be used for ULTRA GI cycle

Cycle/Tray Summary of Non-Clinical Testing

The following performance testing was conducted to verify the ULTRA GI Cycle device functionality.

Table 3. Performance Test Results – STERRAD 100NX Sterilizer

Test	Acceptance Criteria	Results
Sterilization Verification	SAL of 10^{-6} shall be demonstrated.	Pass
Surface Sterilization	All test samples show no growth.	Pass
Mated Surface Sterilization	All test samples show no growth.	Pass
Growth Inhibition	No growth inhibition shall be indicated for processed samples.	Pass
In Use Test	Cycle performance shall be validated using scopes under in-use conditions.	Pass
Biocompatibility	The biological safety of materials shall be demonstrated following exposure to the sterilant agent.	Pass
Simulated Use Test	Microbial performance should be demonstrated under simulated conditions.	Pass
Device Functionality and Material Compatibility	GI Endoscopes shall remain within the manufacturer's functional specifications post processing.	Pass
Final Process Qualification	The critical process parameter values shall conform to the specifications for the STERRAD® 100NX™ Sterilizer Titan Cycle.	Pass
Usability	System must demonstrate it can be used safely and effectively by the intended users, under the expected conditions, without producing hazardous situations or unacceptable use errors.	Pass

Table 4. Performance Test Results – APTIMAX Instrument Tray for ULTRA GI Cycle

Test	Acceptance Criteria	Results
Tray Life Test	Pre-determined target cycle number was set for testing and shall be achieved post completion	Pass
Tray Design Verification	The proposed design must meet the specifications for: 1. Stress/pressure testing 2. Temperature 3. Material 4. Weight	Pass
Manual Cleaning of Tray	Cleaning efficacy results of material shall be below the pre-established limit	Pass

Cycle/Tray Clinical Testing

No clinical data was generated in support of this submission.

Summary

The subject device, STERRAD 100NX Sterilizer with ALLClear Technology with expanded indications, and its predicate device utilize the same technology, sterilization cycles, and sterilization validation methods to sterilize medical devices. Based on the results of the performance testing, the change to the indications of the ULTRA GI Cycle does not raise any new questions of safety or effectiveness. ASP believes the subject STERRAD 100NX Sterilizer with ALLClear Technology, with expanded ULTRA GI Cycle indications, to be as safe and effective as the predicate device. Further, the APTIMAX ULTRA GI Instrument Tray verification testing demonstrates that the device meets the intended use to encase surgical instruments for sterilization in the STERRAD 100NX ULTRA GI Cycle. ASP believes the subject STERRAD 100NX Sterilizer with ALLClear Technology and ULTRA GI Cycle along with the APTIMAX ULTRA GI Instrument Tray to be as safe and effective as their predicate and reference devices.

Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data; the subject device, STERRAD 100NX with ALLClear Technology including the ULTRA GI Cycle indications expansion along with APTIMAX ULTRA GI Instrument Tray, is as safe, as effective, and performs as well as the legally marketed predicate device cleared via K212174 and the APTIMAX Instrument Tray, cleared under K013003.