April 14, 2025

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

Re: K250802
Trade/Device Name: STERRAD® 100NX Sterilizer with ALLClear™ Technology (10104)
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: March 14, 2025
Received: March 14, 2025

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2025.04.14 14:44:09 -04'00'

for: Christopher K. Dugard
Division Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical 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)*
K250802

Device Name
STERRAD® 100NX Sterilizer with ALLClear™ Technology (10104)

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 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 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 1: 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.
• One Dual channel flexible endoscope with two polyethylene and Teflon (polytetrafluoroethylene) lumens that each have an inside diameter of 1 mm or larger and a length of 885 mm or shorter.
Note 2: The validation studies for DUO Cycle was performed using a validation load consisting of 1 dual channel endoscope with ≥1 mm diameter x ≤885 mm long and ≥2.2 mm diameter x ≤835 mm long PTFE/PE lumens, and 1 dual channel endescope with ≥1 mm diameter x ≤670 mm long and ≥2.2 mm diameter x ≤845 mm long PTFE/PE lumens
The STERRAD 100NX Sterilizer ULTRA GI Cycle is designed for sterilization of the following:
• Medical devices, including multi-channel endoscopes (including duodenoscopes), with no more than 4 channels, with lumen dimensions of ≥1mm x ≤1500mm in length, and ≥2mm x ≤1630mm in length.
• One flexible endoscope per tray, and no more than two flexible endoscopes 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 compatible duodenoscopes.

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 for K250802
Advanced Sterilization Products, Inc.
STERRAD™ 100NX Sterilizer with ALLClear™ Technology

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: April 10, 2025

Devices Names

Proprietary Name:	**STERRAD™ 100NX Sterilizer with ALLClear™ Technology (10104)**
Device Common Name:	Hydrogen Peroxide Gas Plasma Sterilization System
Classification Name:	Ethylene Oxide Gas Sterilizer
Product Code:	MLR
Device Class:	Class II
CFR Section:	21 CFR 880.6860

Predicate Devices

STERRAD 100NX Sterilizer with ALLClear Technology K234082 cleared July 5, 2024.

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 five cleared sterilization cycles: STANDARD, FLEX, EXPRESS, DUO and ULTRA GI Cycles.

The STERRAD 100NX Sterilizer with ALLClear Technology described within this submission expands the indications of the DUO Cycle of the STERRAD 100NX Sterilizer to include one dual-channel flexible endoscope with two polyethylene and Teflon (polytetrafluoroethylene) lumens that each have an inside diameter of 1 mm or larger and a length of 885 mm or shorter and with the weight of 3.4 kg (7.4 lbs). There are no other changes to the indications for use for the DUO cycle.

Intended Use/Indications for Use

The intended use of the subject STERRAD 100NX Sterilizer with ALLClear Technology and ULTRA GI has not changed as a result of expanded indications for DUO Cycle. Refer to Table 1 below for a comparison of intended use and indications for use of the predicate and proposed devices.

Technological Characteristics

The technological characteristics associated with the sterilization process for the proposed STERRAD 100NX Sterilizer with ALLClear Technology with expanded indications for the Duo Cycle are equivalent to those of the previously cleared STERRAD 100NX Sterilizer with ALLClear Technology and ULTRA GI cycle; there are no modifications being introduced to alter existing sterilization cycles and other physical features of the subject device.

The predicate device continues to have the same technological characteristics, sterilization performance, and physical traits as the predicate device, STERRAD 100NX Sterilizer with ALLClear Technology and ULTRA GI cycle.

Table 1. Comparison between the subject device and predicate devices

Feature	STERRAD 100NX Sterilizer with ALLClear TechnologyDUO cycle claims expansion Subject Device	STERRAD 100NX Sterilizer with ALLClear Technology and ULTRA GI Cycle K234082 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-	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-	Similar, includes expanded claims for DUO cycle

Feature	STERRAD 100NX Sterilizer with ALLClear TechnologyDUO cycle claims expansion Subject Device	STERRAD 100NX Sterilizer with ALLClear Technology and ULTRA GI Cycle K234082 Predicate Device	Comparison
	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 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 designed for sterilization of medical devices including most flexible	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,	

Feature	STERRAD 100NX Sterilizer with ALLClear TechnologyDUO cycle claims expansion Subject Device	STERRAD 100NX Sterilizer with ALLClear Technology and ULTRA GI Cycle K234082 Predicate Device	Comparison
	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 1: 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. • One Dual channel flexible endoscope with two polyethylene and Teflon (polytetrafluoroethylene) lumens that each have an inside diameter of 1 mm or larger and a length of 885 mm or shorter. Note 2: The validation studies for DUO Cycle was performed using a validation load consisting of 1 dual channel endoscope with 1 mm diameter x 885 mm long and 2.2 mm diameter x 835 mm long PTFE/PE lumens, and 1 dual channel endoscope with 1 mm diameter x 670 mm long and 2.2 mm diameter x 845 mm long PTFE/PE lumens. 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.	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	

Feature	STERRAD 100NX Sterilizer with ALLClear TechnologyDUO cycle claims expansion Subject Device	STERRAD 100NX Sterilizer with ALLClear Technology and ULTRA GI Cycle K234082 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	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	ULTRA GI 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

Cycle Summary of Non-Clinical Testing

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

Table 2. 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
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	Dual channel flexible endoscopes shall remain within established functional specifications post processing.	Pass

Cycle Clinical Testing

No clinical data was generated in support of this submission.

Summary

The subject device, STERRAD 100NX Sterilizer with ALLClear Technology with DUO cycle claims expansion, 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 DUO Cycle does not raise any new questions of safety or effectiveness. ASP believes the subject STERRAD 100NX Sterilizer with ALLClear Technology with DUO cycle claims expansion, to be as safe and effective as the predicate device and reference devices.

Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data; the subject device, STERRAD 100NX with ALLClear Technology with DUO Cycle claims expansion is as safe, as effective, and performs as well as the legally marketed predicate device cleared via K234082.