October 9, 2021

Advanced Sterilization Products, Inc.
Summer Bowman
Senior Regulatory Affairs Specialist
33 Technology Drive
Irvine, California 92618

Re: K212174
Trade/Device Name: STERRAD 100NX Sterilizer with ALLClear Technology
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene oxide gas sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: July 8, 2021
Received: July 12, 2021

Dear Summer Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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

Sincerely,

Clarence W. Murray III -S

Clarence W. Murray, III, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212174

Device Name
STERRAD® 100NX™ Sterilizer with ALLClear® Technology

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*

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**

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.

* A maximum of ten single channel stainless steel lumens, five per tray per sterilization cycle.
** A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load.

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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K212174 510(k) Summary

Advanced Sterilization Products, Inc.
STERRAD® 100NX Sterilizer with ALLClear® Technology

FLEX Cycle Claims Expansion

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

General Information

Submitter Name: Advanced Sterilization Products, Inc.

Address: 33 Technology Drive
Irvine, CA 92618

Contact Person: Summer Bowman
Senior Regulatory Affairs Specialist
Tel: (949) 561-9540
Email: summer.bowman@asp.com

Date Prepared: July 08, 2021

Device Name

Proprietary Name: STERRAD® 100NX Sterilizer with ALLClear® Technology
Common Name: Hydrogen Peroxide Gas Plasma Sterilization System
Classification Name: Ethylene oxide gas sterilizer
Device Class: Class II
Product Code: MLR
CFR Section: 21 CFR 880.6860

Predicate Device

STERRAD® 100NX Sterilizer with ALLClear® Technology cleared under 510(k) K160903 on September 26, 2016.

Device Description

The STERRAD 100NX Sterilizer 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 affect sterilization. The hardware for the STERRAD 100NX Sterilizer consists of a sterilizer chamber, constructed with aluminum, and a variety of instruments and components which are housed in a covered frame. The sterilizer also uses accessories such as reusable instrument trays, and printer paper. The STERRAD 100NX Sterilizer has four cleared sterilization cycles: STANDARD, FLEX, EXPRESS, and DUO Cycles.

An expansion of existing claims is being applied to the FLEX cycle without affecting the technology, software, or other physical features of the subject device.

The STERRAD 100NX Sterilizer with ALLClear Technology described within this submission expands the indications of the FLEX Cycle of the STERRAD 100NX Sterilizer to include single channel flexible endoscopes with extended dimensions from 850 mm in length to 1065 mm in length, when the inside diameter is ≥1 mm. There are no other changes to the indications for use for the FLEX Cycle. The FLEX Cycle is compatible with single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of **1065** mm or shorter[1] **

Technological Characteristics

The technological characteristics associated with the sterilization process for the proposed STERRAD 100NX Sterilizer with ALLClear Technology with expanded indications for the Flex Cycle are equivalent to those of the previously cleared STERRAD 100NX Sterilizer with ALLClear Technology; there are no modifications being introduced to alter existing sterilization cycles.

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.

Intended Use/Indications For Use

The intended use of the subject STERRAD 100NX Sterilizer with ALLClear Technology has not changed as a result of expanded indications for use of the FLEX Cycle. Refer to Table 5.1 to see

[1] A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load.

a comparison of intended use of the predicate and proposed devices. Table 5.1 also exhibits a comparison of the Indications for Use.

Table 5.1 Intended Use/Indications for Use Comparison

	Predicate	Proposed
	STERRAD 100NX Sterilizer with ALLClear Technology K160903	**STERRAD 100NX Sterilizer with ALLClear Technology**
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.	Same
Indications for Use	The STERRAD 100NX Sterilizer 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.	Same
	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.	FSame
	Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer FLEX Scope cycle:	Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD 100NX Sterilizer FLEX Scope cycle:

	Predicate	Proposed
	STERRAD 100NX Sterilizer with ALLClear Technology K160903	**STERRAD 100NX Sterilizer with ALLClear Technology**
	• Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of 850 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 850 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 850 mm flexible endoscopes were validated without any additional load.	• 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 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.	Same

Biocompatibility

The proposed changes to the indications for use do not affect sterilization cycle parameters, sterilant, sterilant injection volume, or types of materials processed in the sterilizer. The previously submitted biocompatibility data for the predicate device (K160903) remains applicable to the subject STERRAD 100NX Sterilizer with ALLClear Technology.

Summary of Non-Clinical Testing

No clinical data was generated in support of this Premarket Notification.

Performance testing was conducted to verify that single channel flexible endoscopes with the expanded lumen claim of ≥ 1 mm diameter x ≤ 1065 mm length can be successfully sterilized in the FLEX cycle of the STERRAD 100NX Sterilizer with AllClear Technology.

Table 5.2 Performance Testing Results

Verification Testing	Description	Pass/Fail
Dose Response	Study demonstrated sterility assurance level of (SAL) of 10^{-6} was reached when processing single channel flexible endoscopes with expanded claim (⩾ 1 mm diameter X ⩽ 1065 mm) in STERRAD 100NX FLEX half-cycle conditions.	Pass
Simulated Use	Study demonstrated sterilization efficacy of flexible endoscopes with proposed claims expansion of ≥1 mm diameter x ≤1065 mm in length when processed in the STERRAD 100NX FLEX cycle.	Pass

The results of the performance testing demonstrate that single channel flexible endoscopes with lumen dimensions of ≥ 1mm x ≤ 1065mm can be sterilized in the FLEX cycle of the STERRAD 100NX Sterilizer.

Summary

The proposed 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 FLEX Cycle does not raise any new questions of safety or effectiveness. ASP believes the subject STERRAD 100NX Sterilizer with ALLClear Technology, with expanded Flex Cycle indications, to be as safe and as effective as the predicate device.

Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the proposed device, STERRAD 100NX with ALLClear Technology with FLEX Cycle indications expansion, is as safe, as effective, and performs as well as or better than the legally marketed device STERRAD 100NX with ALLClear Technology, cleared under K160903.