May 16, 2022

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

Re: K220404
Trade/Device Name: STERRAD® NX Sterilizer with ALLClear™ Technology
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: February 6, 2022
Received: February 14, 2022

Dear Katy Nennig:

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, PhD
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)*
K220404

Device Name
STERRAD® NX™ Sterilizer with ALLClear Technology™

Indications for Use *(Describe)*
The STERRAD NX 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 affect sterilization. The STERRAD NX 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 NX Sterilizer STANDARD Cycle:
• Single-channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 150 mm or shorter.†
• Single-channel stainless steel lumens with an inside diameter of 2 mm or larger and a length of 400 mm or shorter.†
†The validation testing for this lumen size was conducted using a maximum of 10 lumens per load. Your loads should not exceed the maximum number of lumens validated by this testing.
Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD NX Sterilizer ADVANCED Cycle:
• Single-channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 500 mm or shorter. †
• Single-channel PE/PTFE flexible endoscopes with an inside diameter of 1 mm or larger and a length of 1065 mm or shorter.*

Note: With the exception of the flexible endoscopes, the validation studies were performed using a validation load consisting of devices in one instrument tray weighing 10.7 lbs (4.9 kg). The flexible endoscopes were validated without any additional load.**

†The validation testing for this lumen size was conducted using a maximum of 10 lumens per load. Your loads should not exceed the maximum number of lumens validated by this testing.
* Only one flexible endoscope up to 1065 mm long with or without APTIMAX Instrument Tray Holders can be used per cycle, or only one flexible endoscope up to 850 mm long per cycle with or without a STERRAD Instrument Tray Mat. No additional load. Check the medical device manufacturer's instructions for use prior to processing any scope in the STERRAD NX Sterilizer; and check if Instrument tray mats or only tray holders are validated for use with flexible endoscopes longer than 850 mm.

**The validation testing for flexible endoscopes up to 850 mm long was conducted with one endoscope per cycle using a STERRAD Instrument Tray Mat to help protect the endoscope no additional load. The validation testing for flexible endoscopes longer that 850 mm was conducted with one endoscope per cycle using APTIMAX Instrument Tray Holders to assist with device placement and help protect the endoscope: 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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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**510(k) Summary**
**Advanced Sterilization Products, Inc.**
**STERRAD® NX Sterilizer with ALLClear™ Technology**
**ADVANCED Cycle Claims Expansion**

This summary of 510(k) 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: Katy Nennig
Senior Regulatory Affairs Specialist
Tel: (920)254-6370
Email: Katelyn.nennig@asp.com


Date Prepared: May 11th, 2022

## Device Name

| | |
|---|---|
| Proprietary Name: | STERRAD® NX 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® NX Sterilizer with ALLClear® Technology cleared via 510(k) K160818 on September 27, 2016.

## Device Description

The STERRAD NX 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 STERRAD NX Sterilizer has two cleared sterilization cycles, the STANDARD and ADVANCED Cycles.

The sterilizer uses a disposable sterilant cassette that contains the 59% nominal hydrogen peroxide solution in a plastic cell pack and cassette shells. The hydrogen peroxide is concentrated before introducing into the sterilizer chamber and its concentration is monitored during the cycle. The sterilizer cancels the cycle if the hydrogen peroxide monitor data does not meet the specification.

The hardware for the STERRAD NX 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, printer paper, and an optional movable cart. The STERRAD NX Sterilizer can be placed directly on a table, countertop, or on the movable cart.

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

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

**Intended Use/Indications For Use**

The STERRAD NX 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 affect sterilization. The STERRAD NX 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 NX Sterilizer STANDARD Cycle:

- Single-channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 150 mm or shorter.†
- Single-channel stainless steel lumens with an inside diameter of 2 mm or larger and a length of 400 mm or shorter.†

†The validation testing for this lumen size was conducted using a maximum of 10 lumens per load. Your loads should not exceed the maximum number of lumens validated by this testing.

Medical devices, including most flexible endoscopes, with the following materials and dimensions can be processed in the STERRAD NX Sterilizer ADVANCED Cycle:

- Single-channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 500 mm or shorter. †
- Single-channel PE/PTFE flexible endoscopes with an inside diameter of 1 mm or larger and a length of 1065 mm or shorter.*

Note: With the exception of the flexible endoscopes, the validation studies were performed using a validation load consisting of devices in one instrument tray weighing 10.7 lbs (4.9 kg). The flexible endoscopes were validated without any additional load.**

†The validation testing for this lumen size was conducted using a maximum of 10 lumens per load. Your loads should not exceed the maximum number of lumens validated by this testing.

* Only one flexible endoscope up to 1065 mm long with or without APTIMAX Instrument Tray Holders can be used per cycle, or only one flexible endoscope up to 850 mm long per cycle with or without a STERRAD Instrument Tray Mat. No additional load. Check the medical device manufacturer's instructions for use prior to processing any scope in the STERRAD NX Sterilizer; and check if Instrument tray mats or only tray holders are validated for use with flexible endoscopes longer than 850 mm.

**The validation testing for flexible endoscopes up to 850 mm long was conducted with one endoscope per cycle using a STERRAD Instrument Tray Mat to help protect the endoscope no additional load. The validation testing for flexible endoscopes longer that 850 mm was conducted with one endoscope per cycle using APTIMAX Instrument Tray Holders to assist with device placement and help protect the endoscope: no additional load.

**Technological Characteristics Comparison**

The following table provides a comparison of the technological characteristics associated with the sterilization process of the proposed STERRAD NX Sterilizer with ALLClear Technology with expanded indications for the ADVANCED Cycle as compared to those of the previously cleared STERRAD NX with ALLClear Technology.

**Table 5.1 Technological Characteristics Comparison**

| Device & Predicate Device(s): | K160818 | K220404 |
|---|---|---|
| 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. |

| Device & Predicate Device(s): | K160818 | K220404 |
|---|---|---|
| Sterilization Process | Hydrogen peroxide gas plasma | Hydrogen peroxide gas plasma |
| Principle of Operation | Combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes most medical instruments and materials with leaving toxic residues. | Combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes most medical instruments and materials with leaving toxic residues. |
| Pre-Programmed Sterilization Cycles | Two Cycles:<br>STANDARD and ADVANCED | Two Cycles:<br>STANDARD and ADVANCED |
| Material Compatibility (Recommended Materials) | Common materials found in reusable medical devices. All medical devices should be processed in accordance with the medical device manufacturer's recommendations. | Common materials found in reusable medical devices. All medical devices should be processed in accordance with the medical device manufacturer's recommendations. |
| Approximate Cycle Time | STANDARD Cycle: 28 Minutes<br>ADVANCED Cycle: 38 Minutes | STANDARD Cycle: 28 Minutes<br>ADVANCED Cycle: 38 Minutes |
| Hydrogen Peroxide Monitor | Cancels sterilization cycle if the areas under the concentration-time curve or rate constant do not meet predetermined specifications. | Cancels sterilization cycle if the areas under the concentration-time curve or rate constant do not meet predetermined specifications. |
| Temperature | Chamber, Chamber door and vaporizer/condenser thermistors | Chamber, Chamber door and vaporizer/condenser thermistors |
| Pressure | Chamber pressure transducers Chamber atmospheric pressure switch Vaporizer/condenser pressure transducer | Chamber pressure transducers Chamber atmospheric pressure switch Vaporizer/condenser pressure transducer |

**Summary of Non-Clinical Testing**

Performance testing was conducted to verify that single channel flexible endoscopes with the expanded lumen claim of ≥ 1mm diameter x ≤ 1065mm length can be successfully sterilized by the ADVANCED Cycle of the STERRAD NX Sterilizer with ALLClear Technology. No clinical data was generated in support of this submission.

**Table 5.2 Performance Testing Results**

| Testing Methodology | Description | Acceptance Criteria | Results (Pass/Fail) |
|---|---|---|---|
| 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 (K160818) remains applicable to the subject STERRAD NX Sterilizer with ALLClear Technology. | Process residual levels remaining on/in materials used in the sterilizer shall be non-toxic when evaluated by *in vivo* toxicity tests. | Pass |

| Testing Methodology | Description | Acceptance Criteria | Results (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 NX ADVANCED half-cycle conditions.<br>• Study demonstrated a total kill of BIs in the half cycle condition at 1.5 mL of 53% hydrogen peroxide injected.<br>• The results demonstrated an increasing number of sterile Bis corresponding to an increasing injection volume of hydrogen peroxide.<br>• The positive control demonstrated growth and the negative control demonstrated no growth. | • BI Samples from 1.5mL of 53% hydrogen peroxide in half cycles shall be sterile at the end of the incubation period<br>• A trend of increasing number of sterile Bis corresponding to the increasing injection volume of hydrogen peroxide must be seen.<br>• Positive control demonstrates growth and negative control demonstrates no growth | 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 NX ADVANCED cycle.<br>• The spore log reduction was greater than 6 for all test devices.<br>• The positive controls ranged from $1.6 \times 10^6$ to $1.8 \times 10^6$ CFU | • Spore log reduction must be greater than 6 for test devices.<br>• Positive control shall show a combined exhaustive recovery of at least $1 \times 10^6$ CFU | Pass |

The results of performance testing demonstrates that single channel flexible endoscopes with lumen dimensions of ≥ 1mm x ≤ 1065mm can be sterilized by the ADVANCED Cycle of the STERRAD NX Sterilizer.

**Summary**

The subject device, STERRAD NX 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 ADVANCED Cycle does not raise any new questions of safety or effectiveness.

**Conclusion**

The conclusions drawn from the non-clinical performance data demonstrate that the subject device, STERRAD NX with ALLClear Technology including the ADVANCED Cycle indications expansion, is as safe,

as effective, and performs as well or better than the legally marketed predicate device cleared via K160818.