DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

September 26, 2016

Advanced Sterilization Products
Jamie Byun
Senior Regulatory Affairs Specialist
33 Technology Drive
Irvine, California 92617

Re: K160903
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: August 25, 2016
Received: August 29, 2016

Dear Jamie Byun,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang
Acting Director
Division of Anesthesiology, General Hospital, Respiratory, Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160903

Device Name
STERRAD® 100NX Sterilizer with ALLClear™ Technology

Indications for Use *(Describe)*

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.

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 850 mm or shorter**
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.

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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510(k) Summary

Advanced Sterilization Products
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 Division of Ethicon, Inc., a Johnson & Johnson company
Address:	33 Technology Drive Irvine, CA 92618
Contact Person:	Jamie Byun Senior Regulatory Affairs Specialist Tel: (949) 788-2067 Fax: (949) 798-3900 Email: jbyun@its.jnj.com
Date Prepared:	September 22, 2016
510(k) Number:	K160903

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 cleared under 510(k) numbers K071385 (November 19, 2007), K092622 (March 4, 2011), K111377 (September 13, 2012), and K142454 (April 3, 2015).

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 STERRAD 100NX Sterilizer has four cleared sterilization cycles: STANDARD, FLEX, EXPRESS, and DUO Cycles.

For the STANDARD and FLEX cycles, hydrogen peroxide (H_2O_2) vapor is generated by injecting aqueous hydrogen peroxide into an on-board vaporizer where the solution is heated and vaporized, thereby concentrating 59% H_2O_2 to 90% nominal H_2O_2. The H_2O_2 vapor is then introduced into the sterilization chamber under sub-ambient pressure and transformed 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.

For the EXPRESS cycle, the onboard concentration process utilized for STANDARD and FLEX cycles is not used; the subsystem receives hydrogen peroxide solution from the delivery system, vaporizes the liquid and delivers it to the chamber.

For the DUO Cycle, hydrogen peroxide from the STERRAD 100NX Cassette follows a different flow path through the delivery module. The hydrogen peroxide, when withdrawn from the cassette, is temporarily held in the accumulators of the delivery module, and a smaller quantity (1.55 mL, nominal value) of hydrogen peroxide is dispensed or metered into the vaporizer during each of the two half-cycles of the DUO cycle. 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 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. Other major components of the system are constructed from passivated stainless steel, Viton (a copolymer of vinylidene fluoride and hexafluoropropylene), Ultem (polyetherimide), injection molding, and structural foam. The sterilizer also uses accessories such as reusable instrument trays, and printer paper.

The STERRAD 100NX Sterilizer uses a disposable sterilant cassette that contains the 59% nominal hydrogen peroxide solution in a plastic cell pack and cassette shells. The sterilizer cancels the cycle if the hydrogen peroxide monitor data does not meet the pre-defined minimum concentration specification.

The modified STERRAD 100NX Sterilizer with ALLClear Technology described within this submission incorporates enhancements and new features to improve reliability and usability, as briefly described following:

- Load Conditioning Feature: Available for use with the STANDARD, FLEX, and EXPRESS cycles. Reduces canceled cycles by performing load and system checks and executing a load conditioning step prior to starting a sterilization cycle.
- Enhanced Graphical User Interface (GUI): Added information to the error messages enabling users to take actions related to that error message. GUI enhancement also provides more intuitive navigation.
- Improved cassette insertion.
- New Touchscreen Display: Larger, higher resolution, and wider viewing angle.
- New External Panels: Enhance aesthetic appearance and accommodate the larger display.
- Capability for future "ecosystem" connectivity: Will allow communication and integration with future ASP biological indicator reader(s), as well as other potential future communication features.

The technological characteristics associated with the sterilization process for the modified STERRAD 100NX Sterilizer ALLClear Technology are identical to those of the previously cleared STERRAD 100NX Sterilizer; the software and hardware changes associated with the described enhancements and new features do not modify the existing sterilization cycles.

Intended Use/Indications For Use

The intended use of the STERRAD 100NX Sterilizer, as described in the labeling, has not changed as a result of the modification(s) nor are there any differences between the predicate STERRAD 100NX and modified STERRAD 100NX ALLClear Technology 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.

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[1]

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 850 mm or shorter[2]

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.

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.

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

Non-Clinical Data

- **Verification testing** was conducted in support of the enhancements to the STERRAD 100NX Sterilizer that is the subject of this submission; all testing yielded passing results. This testing is summarized in the following table.

Summary of Performance Testing

Verification Testing	Description	Pass/ Fail
Load Check Design Verification	Study demonstrated that the modified device, with load conditioning feature enabled, is able to detect load out-gassing that causes cycle cancellations.	Pass
Load Conditioning Design Verification	Study demonstrated that the modified device with load conditioning feature enabled is effective in reducing load out-gassing.	Pass
Titer Enumeration of STERRAD CYCLESURE® 24 BI With and Without Load Conditioning Feature	Study verified that the load conditioning has no significant impact on the CYCLESURE 24 BI	Pass
Chemical Indicator Functionality Testing	Study verified the functionality of the STERRAD Chemical Indicator (CI) Strip, SEALSURE® Chemical Indicator Tape, Chemical Indicator Disc on the CYCLESURE BI, and Tyvek® self-seal and heat-seal pouches with STERRAD Chemical Indicator following exposure to the load conditioning feature.	Pass
Load Temperature Verification	Study demonstrated that the modified STERRAD 100NX system, with load conditioning feature enabled, does not exceed the load temperature limit.	Pass
Final Process Qualification – STANDARD Cycle	Testing demonstrated that the sterilizer performs consistently within its process specifications with the load conditioning feature enabled.	Pass
Final Process Qualification – FLEX Cycle	Testing demonstrated that the sterilizer performs within its process specifications with the load conditioning feature enabled.	Pass
Final Process Qualification - EXPRESS Cycle	Testing demonstrated that the sterilizer performs within its process specifications with the load conditioning feature enabled.	Pass
H_2O_2 Delivery System Design Verification	Study demonstrated that the cassette insertion modifications allow easier insertion and also detect cassette alignment.	Pass
Panel Subsystem Design Verification	Study verified that the new panels provide appropriate protection, provide appropriate access to the users, and accommodate the other modifications.	Pass
Panel Subsystem Design Verification for Internal Enclosure Air Temperature	Study verified that internal air temperature during operation at maximum ambient temperature is within the temperature allowed for sterilizer operation.	Pass
Panel Materials Testing	Study verified that the effects of 70% isopropyl alcohol (IPA) and hydrogen peroxide on the new panel material are within the acceptable range.	Pass

Verification Testing	Description	Pass/ Fail
Display Assembly Subsystem Design Verification	Study verified that the characteristics of the new display assembly and confirmed compatibility with the modified STERRAD 100NX system.	Pass
System Verification	Study verified new and related system requirements which were impacted by the modifications.	Pass
System Tests (Environmental)	Study verified that the modified device operates reliably and effectively at ambient conditions.	Pass
Summative Usability Testing	Usability testing assessed user interaction with the modified device.	Pass

- **Biocompatibility testing**

  In addition to the biocompatibility data submitted in the predicate device 510(k)s, an additional study was performed to assess residual hydrogen peroxide on worst case medical device materials (known to absorb hydrogen peroxide) following load conditioning in conjunction with an STANDARD sterilization cycle. This study demonstrated that mean residual hydrogen peroxide level was statistically significantly less than the acceptable threshold level.

- **Electromagnetic compatibility (EMC) testing** was conducted to demonstrate that the modified STERRAD 100NX complies with the requirements for radiated and conducted emissions in accordance with the following standards:
  - IEC/EN 60601-1-2:2014 *Medical Electrical Equipment, Part 1: General Requirements for Safety, Section 2: Collateral Standard: Electromagnetic Compatibility*
  - EN 55011 *Group I Class A limits, based on CISPR 11:2010, Group I Class A limits (subset of EN 60601-1-2)*
- **Electrical Safety testing** was undertaken to demonstrate that the modified STERRAD 100NX is electrically and mechanically safe when operated and maintained in accordance with the User's Guide. Based upon this testing, the modified STERRAD 100NX Sterilizer conforms to the applicable sections of the standards listed following:
  - CAN/CSA-C22.2 No. 61010-1:2004 + Update 1:2008 R: 2009 *Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use*
  - CAN/CSA-C22.2 No. 61010-2-040:2007-12 R:2013 *Safety requirements for electrical equipment for measurement, control and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials*
  - UL 61010-1/R:2008-10 *Standard for Safety for Electrical Equipment for Laboratory Use*

- IEC/EN 61010-1:2001 *Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use*
- IEC/EN 61010-2-40:2005 *Particular Requirements for Sterilizers and Washer-disinfectors used to Treat Medical Materials, First Edition*

- **Software verification and validation testing** was conducted and documentation was provided within the submission as recommended by *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005. Unit, Integration, and System level testing were successfully completed.

Clinical Data

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

Summary

The STERRAD 100NX Sterilizer ALLClear Technology and its predicate device, the originally cleared STERRAD 100NX Sterilizer, have the same intended use and indications for use. Further, the STERRAD 100NX Sterilizer with ALLClear Technology utilizes the same technology, sterilant, and cycles to sterilize medical devices as does its predicate device.

Refer to the following table for a comparison between the modified and predicate device characteristics.

Comparison of Device Characteristics		
Characteristic	**Predicate STERRAD 100NX Sterilizer K071385, K092622, K111377 and K142454**	**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
Sterilization Process	Hydrogen peroxide gas plasma	Same
Principle of operation	Combined use of hydrogen peroxide vapor and plasma safely and rapidly sterilizes most medical instruments and materials without leaving toxic residues.	Same
Sterilization Cycles	STANDARD, FLEX, EXPRESS and DUO	Same

Comparison of Device Characteristics		
Characteristic	**Predicate STERRAD 100NX Sterilizer K071385, K092622, K111377 and K142454**	**STERRAD 100NX Sterilizer with ALLClear Technology**
Recommended Materials	Common materials found in reusable medical devices. *All medical devices should be processed in accordance with the medical device manufacturer's recommendations.*	Same
Approximate Total Cycle Time *STANDARD Cycle:*	47 minutes	Same
FLEX Cycle:	42 minutes	Same
EXPRESS Cycle:	24 minutes	Same
DUO Cycle:	60 minutes	Same
Load Conditioning Feature	N/A	Yes
Sterilizer Approx. Weight	906 lbs (single or double door)	Same
Sterilizer External Dimensions	30.1" W x 71" H x 40.2" D (765 mm x 1805 mm x 1020 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)
Sterilizer Internal Dimensions	20.1" W x 16.1" H x 28.9" L (510 mm x 410 mm x 735 mm)	Same
Shelves *Shelf Dimensions*	Upper & Lower: 24.6" x 16.9" (625 mm x 430 mm)	Same
Shelf Weight Capacity	55 lbs (25 kg)	Same
Distance Between Shelves	3.4" (86 mm)	Same
Chamber Volume	Usable: 93.4 liters (3.3 ft^3) Total: 152 liters (5.4 ft^3)	Same
Major Component Materials *Chamber Components*	Aluminum	Same
Shelves	Passivated stainless steel	Same
Chamber Door O-Ring	Viton (copolymer of vinylidene fluoride & hexafluoropropylene)	Same
Injector and Vaporizer	Aluminum, Ultem (Polyetherimide), stainless steel, Viton	Same
Exterior Panels	Structural Foam	Injection molding and Structural Foam

Comparison of Device Characteristics		
Characteristic	**Predicate STERRAD 100NX Sterilizer K071385, K092622, K111377 and K142454**	**STERRAD 100NX Sterilizer with ALLClear Technology**
Operator Interface *Flat Panel Display*	10.4" touch screen TN (Twisted Nematic) LCD	12.1" touch screen IPS (In Plane Switching) LCD
Graphical User Interface	AMD Geode family CPU	Same
Hydrogen Peroxide Monitor	Cancels sterilization cycle if the areas under the concentration-time curve or rate constant do not meet predetermined specifications.	Same
Temperature	Chamber, chamber door and vaporizer/condenser thermistors	Same
Pressure	Chamber pressure transducers Chamber atmospheric pressure switch Vaporizer/condenser pressure transducer	Same
Door sensors	Lock sensor Closed sensor	Same
Connectivity	DTI (Digital Transfer interface) Network connectivity software allows the hospital IT department to connect the sterilizer to a hospital local area network	Same
Accessories	STERRAD 100NX Cassette Test Pack CycleSure® Biological Indicator STERRAD Chemical Indicator (CI) Strip STERRAD SealSure™ CI Tape Tyvek® Pouches Instrument Trays	Same

Conclusion

Based on the intended use, technological characteristics, and non-clinical performance data, the STERRAD 100NX Sterilizer with ALLClear Technology that is the subject of 510(k) K160903 is substantially equivalent to the predicate devices cleared under K071385, K092622, K111377, and K142454.