DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 16, 2017

Advanced Sterilization Products
Nazanin Yacobi
Senior Regulatory Affairs Program Lead
33 Technology Dr.
Irvine, California 92618

Re: K162007
Trade/Device Name: Sterrad Nx Sterilizer
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: July 18, 2016
Received: July 20, 2016

Dear Nazanin Yacobi:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
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)*

Device Name
STERRAD NX® Sterilizer

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†
• An inside diameter of 2 mm or larger and a length of 400 mm or shorter†

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 polyethylene and Teflon (polytetrafluoroethylene) flexible endoscope 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, validation studies were performed using a validation load consisting of one instrument tray weighing 10.7 lbs. The 1 x 850 mm flexible endoscope was validated without any additional load.

†The validation testing for this lumen size was conducted using a maximum of 10 lumens per load.
Hospital loads should not exceed the maximum number of lumens validated by this testing.
*Only one flexible endoscope can be processed per sterilization cycle with or without a silicone mat. 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 NX® Sterilizer with New Vacuum Pump

General Information

Submitter Name: Advanced Sterilization Products
Division of Ethicon, Inc., a Johnson & Johnson company

Address: 33 Technology Drive
Irvine, CA 92618

Contact Person: Nazanin Yacobi
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Date Prepared: February 16, 2017

Device Name

Proprietary Name: STERRAD NX® Sterilizer

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 originally cleared under K042116.

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 a 59% aqueous hydrogen peroxide solution into the vaporizer subassembly where the solution is then concentrated and is vaporized at relatively low temperatures through a process that utilizes a combination of heating and sub-ambient pressures created by an on-board vacuum pump. The vaporized hydrogen

peroxide is then introduced into the chamber under sub-ambient pressure to allow perfusion of the hydrogen peroxide throughout the chamber and, facilitating hydrogen peroxide contact with the surfaces to be sterilized. The vapor in the chamber is transformed into gas plasma using electrical energy. The chamber is then vented to allow the sterilization chamber to return to atmospheric pressure. This process is repeated an additional time to complete a full STERRAD NX Sterilization cycle (i.e., the full sterilization cycle is composed of two identical half-cycles). The STERRAD NX Sterilizer has two cleared sterilization cycles, the STANDARD and ADVANCED Cycles, both of which follow the general process described here.

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. Other major components of the system are constructed from passivated stainless steel, Viton (a copolymer of vinylidene fluoride and hexafluoropropylene), Ultem (polyetherimide), and structural foam. 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, counter top, or on the movable STERRAD NX cart.

The STERRAD NX Sterilizer uses a disposable sterilant cassette that contains a 59% nominal hydrogen peroxide solution in a plastic cell pack and cassette shells. As previously described, the hydrogen peroxide is concentrated before introduction 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 pre-defined minimum concentration specification.

The modified STERRAD NX Sterilizer, which is the subject of this submission, incorporates a new vacuum pump and associated mounting components to improve the pump's durability. The new vacuum pump utilizes an oil warming element to maintain an optimum operating temperature range for the vacuum pump's oil during the periods of pump inactivation in-between reprocessing cycles. This modification will be implemented through hardware changes with no impact on the system software.

The technological characteristics associated with the sterilization process for the modified STERRAD NX Sterilizer are identical to those of the previously cleared STERRAD NX Sterilizer. In addition, the hardware changes associated with the described modification do not affect the cleared sterilization cycles or the manner by which the STERRAD NX Sterilizer is operated by the customer.

Intended Use/Indications For Use

The intended use of the STERRAD NX Sterilizer, as described in the labeling, has not changed as a result of the modification nor are there any differences between the predicate STERRAD NX and modified STERRAD NX 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[1]
- An inside diameter of 2 mm or larger and a length of 400 mm or shorter[1]

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[1]

Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscope 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, validation studies were performed using a validation load consisting of one instrument tray weighing 10.7 lbs. The 1 x 850 mm flexible endoscope was validated without any additional load.

Non-Clinical Data

- **Design verification testing** was conducted to test the modified STERRAD NX Sterilizer (with new vacuum pump) design against applicable design inputs; all testing yielded passing results. This testing is summarized in the following table.

Table 1: Summary of performance testing

Verification Testing	Description	Pass/ Fail
Verification of the new Vacuum Pump in the STERRAD NX System	This study conducted design verification to demonstrate that the new vacuum pump is able to meet applicable design inputs. Testing includes design input factors such as time to warm up across different power settings, pump startup across different power settings, pump current draw, environmental specifications, noise generation, time to pump an enclosed space to a defined pressure, fitment, weight and qualitative verification of the presence of certain features such as a drain valve, a feature by which the pump can be lifted.	Pass

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

[2] Only one flexible endoscope can be processed per sterilization cycle with or without a silicone mat. No additional load.

Verification Testing	Description	Pass/ Fail
Verification of the STERRAD NX STANDARD and ADVANCED Cycles using STERRAD NX Sterilizers Built with the New Vacuum Pumps	This study conducted efficacy testing of the STANDARD and ADVANCED cycles in the modified STERRAD NX Sterilizer to verify that there is no impact to efficacy introduced by the use of the new vacuum pump. No growth was observed on the test BIs with a sterility assurance level (SAL) of 10^{-6} of *Geobacillus stearothermophilus* demonstrating no impact to efficacy.	Pass

- **Biocompatibility testing** data submitted in the predicate device 510(k) continues to be applicable to the modified STERRAD NX Sterilizer as no changes have been made to the sterilization process/cycle parameters or the sterilant (hydrogen peroxide) materials.
- **Electromagnetic compatibility (EMC) testing** data submitted in the predicate device 510(k) continues to be applicable to the modified STERRAD NX Sterilizer. Upon review of the device modification TÜV SÜD America, Inc., the notified body that conducts EMC testing on the STERRAD NX Sterilizer, has concluded that there is no anticipated impact to the results of the previous EMC testing.
- **Electrical Safety testing** was conducted to demonstrate that the modified STERRAD NX is electrically and mechanically safe when operated and maintained in accordance with the User's Guide and the Service Guide. Based upon this testing, the modified STERRAD NX Sterilizer conforms to the applicable sections of the following standards:
    - 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 *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** data submitted in the predicate device's 510(k) continues to be applicable to the modified STERRAD NX Sterilizer as there are no modifications being made to the software of the system. Software verification and validation testing was previously conducted in accordance with *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*, dated May 11, 2005.

Clinical Data

No clinical data is being submitted in support of this Premarket Notification.

Summary

The modified STERRAD NX Sterilizer and its predicate device, the previously cleared STERRAD NX Sterilizer, have the same intended use and indications for use. Further, the modified STERRAD NX Sterilizer utilizes the same technology, performance characteristics, sterilant, and cycles as the predicate device to sterilize medical devices. As the only difference between the modified STERRAD NX and the predicate device is the vacuum pump and associated mounting components, no new questions of safety or efficacy are raised.

Comparison of Device Characteristics		
Characteristic	**Predicate STERRAD NX Sterilizer K042116, K142454 and K151725**	**Modified STERRAD NX Sterilizer**
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 and ADVANCED	Same
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:*	28 minutes	Same
Advanced Cycle:	38 minutes	Same
Approximate Sterilizer Weight	325 lb.	335 lb. (new pump weighs 10 lb. more)
Sterilizer External Dimensions	22.0" W x 33" H x 32" D (558.8 mm x 838.2 mm x 812.8 mm)	Same
Sterilizer Internal Dimensions	12.6" W x 23.6" H x 6.2" L (320 mm x 600 mm x 157 mm)	Same
Shelves *Shelf Dimensions*	Upper & Lower: 23.6" L X 12.3" W (600 mm x 312 mm)	Same
Shelf Weight Capacity	24.3 lb (11 kg)	Same
Distance Between Shelves	3.4" (86 mm)	Same

Comparison of Device Characteristics		
Characteristic	**Predicate STERRAD NX Sterilizer K042116, K142454 and K151725**	**Modified STERRAD NX Sterilizer**
Chamber Volume	Usable: 30 liters (1.1 ft^3) Total: 51.3 liters (1.8 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	Same
Operator Interface *Flat Panel Display*	6.4" touch screen TFT (thin-film transistor) LCD	Same
Graphical User Interface	Geode SC2200 266 MHz	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 Sensors	Chamber, chamber door and vaporizer/condenser thermistors	Same
Pressure Sensors	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 NX Cassette Test Pack CycleSure® Biological Indicator STERRAD Chemical Indicator Strip STERRAD SealSure™ Chemical Indicator Tape Tyvek® Pouches Instrument Trays	Same

Conclusion

Based on the intended uses, technological characteristics and non-clinical performance data, the subject device of this special 510(k) is substantially equivalent to the predicate device cleared under K042116, K142454 and K151725.