K111377

510(k) Summary

SEP 13 2012

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products, Division of Ethicon, Inc.
a Johnson & Johnson company
33 Technology Drive
Irvine, CA 92618

Contact Person
Nancy Chu
Manager, Regulatory Affairs
Tel: (949) 453-6435
Fax: (949) 789-3900

September 10, 2012

1 CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Sterilizer, Class II
Common/Usual Name:	Hydrogen Peroxide Gas Plasma Sterilization System
Product Classification:	Sterilizer, Class II
Classification Number:	21 CFR 880.6860
Proprietary Name:	STERRAD® 100NX® Sterilizer with DUO Cycle

2 PREDICATE DEVICES

STERRAD® 100NX® Sterilization System [K071385]
STERRAD® 100S Sterilization System [K991999, K023290]

3 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:**

P. 1 of 4

- 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.

*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.

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 1mm or larger and a length of 875mm 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.

4 DESCRIPTION OF DEVICE

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 three previously cleared cycles (STANDARD, FLEX, EXPRESS) and the new optional additional DUO Cycle.

The hardware for the STERRAD® 100NX® Sterilizer consists of a sterilization chamber and a variety of instruments and components which are housed in a covered frame. The sterilizer system also uses accessories such as a disposable sterilant cassette, reusable instrument trays, and printer paper.

5 TABLE 5-1: COMPARISION BETWEEN SUBJECT DEVICE AND PREDICATES

CHARACTERISTICS	SUBJECT DEVICE	PREDICATE DEVICES	
	STERRAD® 100NX® DUO CYCLE	**STERRAD® 100S CYCLE**	**STERRAD® 100NX® FLEX CYCLE**
Base System	STERRAD® 100NX® Sterilizer	STERRAD® 100S Sterilizer	STERRAD® 100NX® Sterilizer
Hydrogen peroxide, 59%	Yes	Yes	Yes, with concentration process
Hydrogen peroxide delivery	STERRAD® 100NX® Cassette and metered through Delivery Module	STERRAD® 100S cassette	STERRAD® 100NX® Cassette
Disposal of hydrogen peroxide after 10 days of on-board storage	Hydrogen peroxide clearance process, initiated by user	Cassette has to be ejected by user	Cassette has to be ejected by user
Cycle Time, approximate	60 minutes	54 minutes	42 minutes
Load Type	Two flexible endoscopes with accessories; 1x875mm PE/PTFE lumen	No flexible endoscopes	Two flexible endoscopes only; 1x850mm PE/PTFE lumen
Load Weight, lbs	13.2	Not defined	21.4

6 SUMMARY OF NONCLINICAL TESTS

Validation Testing

Testing was performed using the "overkill" approach utilizing *G. stearothermophilus* spores. Table 6-1 identifies the validation studies performed and the results obtained.

TABLE 6-1: VALIDATION STUDIES

STUDY	RESULTS
Dose Response with Biological Model (1 x 875 mm Flexible Endoscope	Passed
Surface Sterilization	Passed
Mated Surface Sterilization	Passed
1 x 875 mm Flexible Endoscope Validation	Passed
Bacteriostasis Testing in the DUO Cycle	Passed
In Use Testing – 1 x 875 mm Flexible Endoscopes and Accessories	Passed
Simulated Use Testing	Passed
Toxicity Testing of Materials	Passed
Device Functionality and Material Compatibility	Passed
Process Reproducibility	Passed

7 OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the STERRAD® 100NX® DUO Cycle is safe and effective for sterilization of medical devices within the indications for use for the sterilizer and establish equivalence of the STERRAD® 100NX® DUO Cycle to the predicate devices, the STERRAD® 100NX® Sterilizer FLEX Cycle and the STERRAD® 100S Sterilizer.

P. 4 of 4

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ms. Nancy Chu
Manager, Regulatory Affairs
Advanced Sterilization Products, Division of Ethicon, Incorporated
33 Technology Drive
Irvine, CA 92618

SEP 13 2012

Re: K111377
Trade/Device Name: STERRAD® 100NX™ Sterilizer with DUO Cycle
Regulation Number: 21 CFR §880.6860
Regulation Name: Ethylene Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: September 10, 2012
Received: September 12, 2012

Dear Ms. Chu:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K111377

Indications for Use

510(k) Number (if known): K111377

Device Name: STERRAD® 100NX® Sterilizer with DUO Cycle

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Prescription Use _____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use __√__ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
)ivision of Anesthesiology, General Hospital
.:ntection Control, Dental Devices

510(k) Number: K 111377