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

April 3, 2015

Advanced Sterilization Products
Sun Choi
Regulatory Affairs Specialist
33 Technology Dr.
Irvine, California 92618

Re: K142454
Trade/Device Name: STERRAD® NX® Sterilizer, STERRAD® 100NX® Sterilizer
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: II
Product Code: MLR
Dated: March 4, 2015
Received: March 6, 2015

Dear Ms. Choi,

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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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 on last page.

510(k) Number *(if known)*
K142454

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*

†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.

Note: With the exception of the 1 x 850 mm flexible endoscopes, the 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.

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)

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FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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 on last page.

510(k) Number *(if known)*
K142454

Device Name
STERRAD® 100NX® Sterilizer

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.

*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)

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Indications for Use

Form Approved: OMB No. 0910-0120
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See PRA Statement on last page.

510(k) Number *(if known)*
K142454

Device Name
STERRAD® 100NX® Sterilizer

Indications for Use *(Describe)*

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.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

I. SUBMITTER

Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618

Contact Person: Sun Choi
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Tel: (949) 453-6378
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Date Prepared:
March 27, 2015

II. DEVICE

Name of Device:	STERRAD® NX® and STERRAD® 100NX® Sterilizers
Common or Usual Name:	Hydrogen Peroxide Gas Plasma Sterilization System
Classification Name:	Ethylene Oxide Gas Sterilizer (21 CFR 880.6860)
Regulatory Class:	II
Product Code:	MLR

III. PREDICATE DEVICE

STERRAD® NX® Sterilization System with STANDARD and ADVANCED Cycles	K042116
STERRAD® 100NX® Sterilization System with	
STANDARD and FLEX Cycles	K071385
EXPRESS Cycle	K092622
DUO Cycle	K111377

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The STERRAD® NX® and 100NX® Sterilizers are self-contained stand-alone systems of hardware and software designed to sterilize medical instruments and devices using a hydrogen peroxide 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 and transforming the vapor into a gas plasma using electrical energy. The STERRAD® NX® and 100NX® are controlled by software running on an onboard microprocessor. The software is designed to control the sterilizer and provide an interface for user interaction with the sterilizer.

The network connectivity software revision that is the basis for this 510(k) premarket notification allows the Hospital IT Department to connect the STERRAD® NX® or STERRAD® 100NX® to a Hospital Local Area Network (LAN) for transfer of cycle parameters to a server and then, if desired, to an Instrument Tracking System. The software has been designed for ease of configuration using Dynamic Host Configuration Protocol **(**DHCP**)**. The cycle information will be available in Portable Document Format (PDF) and Comma Separated Values (CSV) formats and transmitted using Transmission Control Protocol/Internet Protocol (TCP/IP). The network digital information will be identical to the existing cycle information printed out by the devices after each cycle (PDF file) and the existing electronic delimited data (CSV file) that can be downloaded through the USB port.

The software revision has the following performance features:

- It can be configured automatically or manually
- It will be activated only upon the request of the User
- Once it is activated, the User can turn it off and back on
- It will have diagnostic tools for network troubleshooting
- It will notify the User of an unsuccessful transmission

The associated accessories include:

- Network cable

V. INDICATIONS FOR USE

STERRAD® NX® Sterilizer

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*

†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.

Note: With the exception of the 1 x 850 mm flexible endoscopes, the 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.

STERRAD® 100NX® Sterilizer

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.

*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 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The technological characteristics of the predicate devices (STERRAD® NX® and STERRAD® 100NX®) are identical to the devices that are the subject of this 510(k) with the exception of the differences in the software revision for network connectivity and an upgraded CPU with controller board. Design, materials, and functions of the sterilizers have not changed. Refer to Table 1 and Table 2 for comparison between modified and predicate devices for the STERRAD® NX® and STERRAD® 100NX®, respectively.

Table 1: STERRAD® NX® - Comparison Table for Modified Devices vs. Predicate Devices

	Modified Device: STERRAD® NX® Sterilizer	**Predicate Device: STERRAD® NX® Sterilizer (K042116)**	**Comparison**
Intended Use	The STERRAD® Sterilizers are 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	The STERRAD® Sterilizers are 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	Same

	Modified Device: STERRAD® NX® Sterilizer	Predicate Device: STERRAD® NX® Sterilizer (K042116)	Comparison
	instruments sensitive to heat and moisture.	instruments sensitive to heat and moisture.	
Indications for Use	Refer to **Section V, Indications for Use** of this 510(k) Summary.	Refer to **Section V, Indications for Use** of this 510(k) Summary.	Same
Technological Characteristics	The STERRAD® NX® is a hydrogen peroxide gas plasma sterilizer designed to sterilize medical instruments and devices using a hydrogen peroxide 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 and transforming the vapor into a gas plasma using electrical energy. The network connectivity software allows the hospital IT department to connect the sterilizer to a hospital local area network for transfer of cycle parameters to a server and then, if desired, to an instrument tracking system. **The software has been revised for ease of configuration using Dynamic Host Configuration Protocol (DHCP) for network connectivity and an upgraded CPU with controller board.**	The STERRAD® NX® is a hydrogen peroxide gas plasma sterilizer designed to sterilize medical instruments and devices using a hydrogen peroxide 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 and transforming the vapor into a gas plasma using electrical energy. The network connectivity software allows the hospital IT department to connect the sterilizer to a hospital local area network for transfer of cycle parameters to a server and then, if desired, to an instrument tracking system.	Same with the differences shown in **bold font.**
Materials	The chamber and door are constructed with aluminum. The cassette contains the 59% nominal hydrogen peroxide solution in the plastic cell pack and cassette shells.	The chamber and door are constructed with aluminum. The cassette contains the 59% nominal hydrogen peroxide solution in the plastic cell pack and cassette shells.	Same
Design Features	The sterilizer concentrates the hydrogen peroxide. The hydrogen peroxide concentration is monitored during the cycle and the sterilizer cancels the cycle if the hydrogen peroxide monitor data does not meet the specification.	The sterilizer concentrates the hydrogen peroxide. The hydrogen peroxide concentration is monitored during the cycle and the sterilizer cancels the cycle if the hydrogen peroxide monitor data does not meet the specification.	Same
Sterilizer Functions	Logout is used when the current operator is finished using the sterilizer. When Logout is selected, login is required before using the sterilizer. System Summary displays the System Summary file and allows operator to print a copy. Cycle History displays the Select Cycle History screen. This screen allows operator to select a cycle history file and view or print it.	Logout is used when the current operator is finished using the sterilizer. When Logout is selected, login is required before using the sterilizer. System Summary displays the System Summary file and allows operator to print a copy. Cycle History displays the Select Cycle History screen. This screen allows operator to select a cycle history file and view or print it.	Same

	Modified Device: STERRAD® NX® Sterilizer	Predicate Device: STERRAD® NX® Sterilizer (K042116)	Comparison
	Additional Utilities is available only to operators with Supervisor-level access. It displays the Additional Utilities Menu.	Additional Utilities is available only to operators with Supervisor-level access. It displays the Additional Utilities Menu.	

Table 2: STERRAD® 100NX® - Comparison Table for Modified Devices vs. Predicate Devices

	Modified Device: STERRAD® 100NX® Sterilizer	Predicate Devices: STERRAD® 100NX® Sterilizer (K071385 for STANDARD and Flex Cycles, K092622 for EXPRESS Cycle, K111377 for DUO Cycle)	Comparison
Intended Use	The STERRAD® Sterilizers are 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.	The STERRAD® Sterilizers are 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	Refer to **Section V, Indications for Use** of this 510(k) Summary.	Refer to **Section V, Indications for Use** of this 510(k) Summary.	Same
Technological Characteristics	The STERRAD® 100NX® is a hydrogen peroxide gas plasma sterilizer designed to sterilize medical instruments and devices using a hydrogen peroxide 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 and transforming the vapor into a gas plasma using electrical energy. The network connectivity software allows the hospital IT department to connect the sterilizer to a hospital local area network for transfer of cycle parameters to a server and then, if desired, to an instrument tracking system. **The software has been revised for ease of configuration using Dynamic Host Configuration Protocol (DHCP) for network connectivity and an upgraded CPU with controller board.**	The STERRAD® 100NX® is a hydrogen peroxide gas plasma sterilizer designed to sterilize medical instruments and devices using a hydrogen peroxide 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 and transforming the vapor into a gas plasma using electrical energy. The network connectivity software allows the hospital IT department to connect the sterilizer to a hospital local area network for transfer of cycle parameters to a server and then, if desired, to an instrument tracking system.	Same with the differences shown in **bold font.**
Materials	The chamber and door are constructed with aluminum. The cassette contains the 59% nominal hydrogen peroxide solution in the plastic cell pack and cassette shells.	The chamber and door are constructed with aluminum. The cassette contains the 59% nominal hydrogen peroxide solution in the plastic cell pack and cassette shells.	Same

	Modified Device: STERRAD® 100NX® Sterilizer	Predicate Devices: STERRAD® 100NX® Sterilizer (K071385 for STANDARD and Flex Cycles, K092622 for EXPRESS Cycle, K111377 for DUO Cycle)	Comparison
Design Features	The sterilizer concentrates the hydrogen peroxide for Standard and Flex Cycles. The hydrogen peroxide concentration is monitored during the cycle and the sterilizer cancels the cycle if the hydrogen peroxide monitor data does not meet the specification.	The sterilizer concentrates the hydrogen peroxide for Standard and Flex Cycles. The hydrogen peroxide concentration is monitored during the cycle and the sterilizer cancels the cycle if the hydrogen peroxide monitor data does not meet the specification.	Same
Sterilizer Functions	Logout is used when the current operator is finished using the sterilizer and the option is enabled. When Logout is selected, the operator must re-login to use the sterilizer. Cycle History displays the Select Cycle History screen. This screen allows the operator to select a cycle history file and view or print it. Utilities are available only to operators with Supervisor-level access. It displays the Additional Utilities Menu. Door Open opens the active door. Door Close closes the active door.	Logout is used when the current operator is finished using the sterilizer and the option is enabled. When Logout is selected, the operator must re-login to use the sterilizer. Cycle History displays the Select Cycle History screen. This screen allows the operator to select a cycle history file and view or print it. Utilities are available only to operators with Supervisor-level access. It displays the Additional Utilities Menu. Door Open opens the active door. Door Close closes the active door.	Same

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Since the cited changes to the predicate devices do not affect the design or materials of the devices, biocompatibility testing was not required.

Electrical safety and electromagnetic compatibility (EMC)

The STERRAD® NX® and 100NX® Sterilizers with the upgraded CPU and controller board were tested for Radiated and Conducted Emissions according to the Standards shown in the table below. All test results passed the requirements of the Standards (Table 3).

Table 3: Testing of STERRAD® NX® and 100NX® Sterilizers for Radiated and Conducted Emissions

Test Description	Standard	Pass/Fail
Radiated Emissions	CISPR 11:2009 (Amended by A1:2010) Class A	Pass
Radiated Emissions	EN 60601-1-2:2007 Class A	Pass
Conducted Emissions	CISPR 11:2009 (Amended by A1:2010) Class A	Pass
Conducted Emissions	EN 60601-1-2:2007 Class A	Pass

The STERRAD® NX® and 100NX® Sterilizers were evaluated for safety under the standards listed below. The testing, conducted to the set of standards, provided a standardized level of assurance that the system is electrically and mechanically safe when operated and maintained in accordance with the STERRAD® User Guide.

- CAN/CSA-C22.2 No.:61010-1/R: 2009; Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use.

- 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 61010-2-240 Particular requirements for sterilizers and washer-disinfectors used to treat medical materials, First Ed., 2005

- IEC/EN 60601-1-2: 2007 CLASS A; 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 11:2009, Group I Class A limits (subset of EN 60601-1-2)

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate " level of concern since prior to mitigation of hazards a failure of the software could result in Minor Injury, either to a patient or to a user of the device.

Mechanical and acoustic testing

No additional mechanical testing was performed since the only change in the predicate devices was the upgraded CPU with controller board and the software upgrade.

Animal Study

No animal studies were conducted.

Clinical Studies

No clinical studies were conducted.

VIII. CONCLUSIONS

The changes to the predicate devices were a software revision and the use of a newer version of the CPU with the associated control board. Software verification and validation performed with these changes demonstrated that the modified devices will perform as intended under the specified use conditions. Therefore Advanced Sterilization Products considers the STERRAD® NX® and STERRAD® 100NX® with revised software, CPU and controller board to be substantially equivalent to their predicates.