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

January 13, 2016

Advanced Sterilization Products
Ms. Sun Choi
Regulatory Affairs Specialist IV
33 Technology Drive
Irvine, CA 92618

Re: K151725
Trade/Device Name: STERRAD® NX® Sterilizer
STERRAD® 100NX® Sterilizer
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: MLR
Dated: December 14, 2015
Received: December 17, 2015

Dear Ms. Sun 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" (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 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)*
K151725

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)

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)*

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)*
K151725

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)

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)*

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)*
K151725

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
K151725

I. SUBMITTER

Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618

Contact Person: Sun Choi
Regulatory Affairs Specialist IV
Telephone: (949) 453-6378
Fax: (949) 798-3900

Date Prepared: January 7, 2016

II. DEVICE

Name of Device: STERRAD® NX® Sterilizer and STERRAD® 100NX® Sterilizer
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 Sterilizer and STERRAD 100NX Sterilizer, K142454

The subject and predicate devices are manufactured by Advanced Sterilization Products.

IV. DEVICE DESCRIPTION

STERRAD NX Sterilizer

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, counter top, or on the movable cart.

STERRAD 100NX Sterilizer

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).

The sterilizer uses a disposable sterilant cassette that contains the 59% nominal hydrogen peroxide solution in a plastic cell pack and cassette shells. For the Standard and Flex Cycles, the hydrogen peroxide is concentrated before introducing into the sterilizer chamber. For the EXPRESS and DUO Cycles, the concentration process is not used. For all four 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 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.

Network Connectivity

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 software has the network connectivity feature that 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 basis for this 510(k) premarket notification is to offer the software revision that enables the network connectivity for the STERRAD NX and 100NX Sterilizers that were already placed on the market with the previous version of microprocessor. This proposed software revision includes the same software codes which were cleared for the systems under K142454 and has the same performance features as compared to the predicate devices as follows:

- 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; and
- It will notify the user of an unsuccessful transmission.

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 subject devices have the same intended use, indications for use, materials, design features, and sterilizer functions as the predicate devices. Both the subject and predicate devices share the same technological characteristics with the exception of different versions of the microprocessor module.

The predicate devices use a later version microprocessor module due to the obsolescence of the previous version by the supplier. ASP plans to offer the software upgrade that enables the network connectivity for the subject devices, i.e., the STERRAD NX and STERRAD 100NX Sterilizers that were manufactured and distributed with the previous version of the microprocessor module.

Refer to Table 1 and Table 2 for comparison between subject and predicate devices for the STERRAD NX and STERRAD 100NX, respectively.

Table 1: STERRAD NX - Comparison Table for Subject Device vs. Predicate Device

	Predicate Device: STERRAD NX Sterilizer (K142454)	**Subject Device: STERRAD NX Sterilizer (K151725)**
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.	Same as predicate
Indications for Use	Refer to **Section V, Indications for Use** of this 510(k) Summary.	Same as predicate
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	Same as predicate with the exception of an earlier microprocessor module version

	Predicate Device: STERRAD NX Sterilizer (K142454)	Subject Device: STERRAD NX Sterilizer (K151725)
	designed for ease of configuration using Dynamic Host Configuration Protocol (DHCP) for network connectivity.	
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.	Same as predicate
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.	Same as predicate
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. Additional Utilities is available only to operators with Supervisor-level access. It displays the Additional Utilities Menu.	Same as predicate

Table 2: STERRAD 100NX - Comparison Table for Subject Device vs. Predicate Device

	Predicate Devices: STERRAD 100NX Sterilizer (K142454)	Subject Device: STERRAD 100NX Sterilizer (K151725)
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.	Same as predicate
Indications for Use	Refer to **Section V, Indications for Use** of this 510(k) Summary.	Same as predicate

	Predicate Devices: **STERRAD 100NX Sterilizer** **(K142454)**	**Subject Device:** **STERRAD 100NX Sterilizer** **(K151725)**
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 designed for ease of configuration using Dynamic Host Configuration Protocol (DHCP) for network connectivity.	Same as predicate with the exception of an earlier microprocessor module version
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.	Same as predicate
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.	Same as predicate
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.	Same as predicate

VII. PERFORMANCE DATA

The subject devices have the same intended use, indications for use, materials, design features, technological characteristics, and sterilizer functions as the predicate devices. The following studies were performed in support of the substantial equivalence determination between the subject and predicate devices.

Electrical safety and electromagnetic compatibility (EMC)

The subject devices 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 +A1:2010 Class A	Pass
Radiated Emissions	EN 60601-1-2:2007 Class A	Pass
Conducted Emissions	CISPR 11:2009 +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 (R2009); *Safety Requirements for Electrical Equipment for Measurement, Control, and Laboratory Use*.
- UL 61010-1 (R2008); *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 61010-2-040:2005, *Particular requirements for sterilizers and washer-disinfectors used to treat medical materials,First Ed.*
- IEC/EN 60601-1-2:2007, CLASS A; *Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.*
- EN 55011:2009 +A1:2010, Group I Class A limits, based on CISPR 11:2009, Group I Class A limits (subset of EN 60601-1-2), *Industrial, Scientific and Medical Equipment – Radio-frequency Disturbance Characteristics – Limits and Methods of Measurement.*

Software Verification and Validation Testing

Software verification and validation testing was conducted as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." All testing met the predefined acceptance criteria. 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.

VIII. CONCLUSIONS

The subject devices have the same intended use and technological characteristics as the predicate devices; additionally, non-clinical performance testing demonstrates equivalent performance between the subject and predicate devices. Therefore, based on the intended uses, technological characteristics, and non-clinical performance data, the subject devices (K151725) are substantially equivalent to the predicate devices cleared under K142454.