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

December 19,2014

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

Re: K141693
Trade/Device Name: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: November 20, 2014
Received: November 21, 2014

Dear 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" (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,

Susan Runner DDS, MA

Erin Keith, MS
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)*
K141693

Device Name
Tyvek® Pouch/Roll with STERRAD® Chemical Indicator

Indications for Use *(Describe)*
(Page 1 of 2)

Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD® Sterilization Systems and Cycles, in a single or double pouch configuration, and to indicate, by color change, that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll maintains sterility until the pouch/roll is used; in the United States, this is for a period of 30 days.

The STERRAD® Sterilization Systems and Cycles that can be used are shown in Table 1. The product codes for all Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are listed in Table 2.

The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilization Systems.

Table 1: Indications for Use

STERRAD® / Cycle	Single-channel stainless steel lumens	Other lumens	Load requirements
STERRAD® 100S	≥1 mm ID x ≤125 mm long ≥2 mm ID x ≤250 mm long ≥3 mm ID x ≤400 mm long	Metal and nonmetal ≥6 mm ID x ≤310 mm long	≤10 lumens per load
STERRAD® 50	≥1 mm ID x ≤125 mm long ≥2 mm ID x ≤250 mm long ≥3 mm ID x ≤400 mm long	Metal and nonmetal ≥6 mm ID x ≤310 mm long	≤10 lumens per load
STERRAD® 200	≥1 mm ID x ≤125 mm long ≥2 mm ID x ≤250 mm long ≥3 mm ID x ≤400 mm long	Teflon® and polyethylene ≥6 mm ID x ≤310 mm long	≤12 lumens per load ≤36.48 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)*

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)*
K141693

Device Name
Tyvek® Pouch/Roll with STERRAD® Chemical Indicator

Indications for Use *(Describe)*
(Page 2 of 2)

Table 1: Indications for Use (continued)

STERRAD® / Cycle		Single-channel stainless steel lumens	Other lumens	Load requirements
STERRAD® NX®	Standard	≥1 mm ID x ≤150 mm long ≥2 mm ID x ≤400 mm long	N/A	≤10 lumens per load ≤10.7 lbs
	Advanced	≥1 mm ID x ≤500 mm long	N/A	≤10 lumens per load ≤10.7 lbs
STERRAD® 100NX®	Standard	≥0.7 mm ID x ≤500 mm long	N/A	≤10 lumens per load ≤21.4 lbs
	EXPRESS	N/A	N/A	≤10.7 lbs on bottom shelf only
	DUO	N/A	N/A	Accessory devices (e.g., cameras and light cords) only 2 cameras maximum

Table 2: Product Codes for Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator

Product Type	Product Codes
Tyvek® Self-Seal Pouches with STERRAD® Chemical Indicator (123XX)	12320, 12326, 12335, 12332, 12342, 12340, 12348, 12356
Tyvek® Rolls with STERRAD® Chemical Indicator (124XX)	12407, 12410, 12415, 12420, 12425, 12435, 12442, 12450
Tyvek® Heat-Seal Pouches with STERRAD® Chemical Indicator (125XX)	12521, 12526, 12532, 12541, 12548

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)*

510(k) Summary

Applicant's Name, Address, Telephone, FAX, Contact Person
Advanced Sterilization Products
33 Technology Drive
Irvine, CA 92618

Establishment Registration Number: 2084725

Contact Person
Sun Choi
Regulatory Affairs Specialist IV
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(949) 453-6378 (Telephone)
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Date: December 19, 2014

1. CLASSIFICATION, COMMON OR USUAL NAME, DEVICE NAME

Classification Name:	Sterilization Wrap Sterilization Process Indicator
Common/Usual Name:	Sterilization Pouch / Roll with Chemical Indicator
Product Classification:	Class II
Product Code:	FRG / JOJ
Panel:	General Hospital
Classification Regulation:	21 CFR 880.6850 21 CFR 880.2800
Proprietary Name:	Tyvek® Pouch/Roll with STERRAD® Chemical Indicator

2. PREDICATE DEVICES

The predicate device [510(k) Notification K112087, cleared October 15, 2012] is the Tyvek® Pouch/Roll with STERRAD® Chemical Indicator, for use in the STERRAD® 100NX® Sterilizer.

3. INTENDED USE

Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD® Sterilization Systems and Cycles, in a single or double pouch configuration, and to indicate, by color change, that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll maintains sterility until the pouch/roll is used; in the United States, this is for a period of 30 days.

The STERRAD® Sterilization Systems and Cycles that can be used are shown in Table 1. The product codes for all Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are listed in Table 2.

The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilization Systems.

Table 1: Indications for Use

STERRAD® / Cycle		Single-channel stainless steel lumens	Other lumens	Load requirements
STERRAD® 100S		≥1 mm ID x ≤125 mm long ≥2 mm ID x ≤250 mm long ≥3 mm ID x ≤400 mm long	Metal and nonmetal ≥6 mm ID x ≤310 mm long	≤10 lumens per load
STERRAD® 50		≥1 mm ID x ≤125 mm long ≥2 mm ID x ≤250 mm long ≥3 mm ID x ≤400 mm long	Metal and nonmetal ≥6 mm ID x ≤310 mm long	≤10 lumens per load
STERRAD® 200		≥1 mm ID x ≤125 mm long ≥2 mm ID x ≤250 mm long ≥3 mm ID x ≤400 mm long	Teflon® and polyethylene ≥6 mm ID x ≤310 mm long	≤12 lumens per load ≤36.48 lbs
STERRAD® NX®	Standard	≥1 mm ID x ≤150 mm long ≥2 mm ID x ≤400 mm long	N/A	≤10 lumens per load ≤10.7 lbs
	Advanced	≥1 mm ID x ≤500 mm long	N/A	≤10 lumens per load ≤10.7 lbs
STERRAD® 100NX®	Standard	≥0.7 mm ID x ≤500 mm long	N/A	≤10 lumens per load ≤21.4 lbs
	EXPRESS	N/A	N/A	≤10.7 lbs on bottom shelf only
	DUO	N/A	N/A	Accessory devices (e.g., cameras and light cords) only 2 cameras maximum

Table 2: Product Codes for Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator

Product Type	Product Codes
Tyvek® Self-Seal Pouches with STERRAD® Chemical Indicator (123XX)	12320, 12326, 12335, 12332, 12342, 12340, 12348, 12356
Tyvek® Rolls with STERRAD® Chemical Indicator (124XX)	12407, 12410, 12415, 12420, 12425, 12435, 12442, 12450
Tyvek® Heat-Seal Pouches with STERRAD® Chemical Indicator (125XX)	12521, 12526, 12532, 12541, 12548

4. DESCRIPTION OF DEVICE

The proposed pouches are constructed from Tyvek® / plastic films, with the STERRAD® Chemical Indicator printed onto the Tyvek® film. The self-seal pouch permits sealing of the pouch without need of heat-sealing equipment, while the heat sealed pouches and rolls are heat sealed prior to processing in the STERRAD® Sterilization Systems.

The STERRAD® Chemical Indicator offers an additional way to verify processing in the sterilization cycle. The Chemical Indicator should be used in addition to, not in place of, the biological indicator. STERRAD® Chemical Indicators do not signify sterilization; they only indicate that the indicator has been exposed to the hydrogen peroxide. The color of the Chemical Indicator changes from red to yellow (or lighter) when exposed to hydrogen peroxide. Refer to Table 3 for comparison between proposed and predicate devices.

Table 3: Comparison Table for Proposed Device vs. Predicate Device

	Proposed Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator	**Predicate Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (K112087)**	**Comparison**
Intended Use	The Tyvek® Pouch/Roll with STERRAD® Chemical Indicator is intended to enclose a medical device that is to be sterilized in the STERRAD® Sterilization System, and to show that the pouch/roll has been exposed to hydrogen peroxide during the sterilization process.	The Tyvek® Pouch/Roll with STERRAD® Chemical Indicator is intended to enclose a medical device that is to be sterilized in the STERRAD® Sterilization System, and to show that the pouch/roll has been exposed to hydrogen peroxide during the sterilization process.	Same

	Proposed Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator	**Predicate Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (K112087)**	**Comparison**
Indications for Use	Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD® Sterilization Systems and Cycles, in a single or double pouch configuration, and to indicate, by color change, that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll maintains sterility until the pouch/roll is used; in the United States, this is for a period of 30 days. The STERRAD® Sterilization Systems and Cycles that can be used are shown in Table 1. The product codes for all Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are listed in Table 2. The pouches and rolls are printed with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilization Systems.	Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator are intended to be used to enclose medical devices that are to be terminally sterilized in the STERRAD® 100NX® Sterilizer and to indicate, by color change that the pouch has been exposed to sterilant. After completion of the sterilization process, the pouch/roll maintains sterility until the seal of the pouch/roll is opened; in the United States, this is for a period of 30 days. The pouches and rolls are printed· with a chemical indicator bar which is a process indicator (ISO 11140-1:2005) that changes from red to yellow (or lighter) when exposed to hydrogen peroxide vapor during processing in the STERRAD® Sterilization Systems.	Additional indications have been included in the Indications for Use for the proposed device. Clarification added for packaging configuration.
Materials of Construction	Tyvek® and transparent plastic film	Tyvek® and transparent plastic film	Same

	Proposed Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator	Predicate Device: Tyvek® Pouch/Roll with STERRAD® Chemical Indicator (K112087)	Comparison
Pouch Types	Self Seal Pouch (123XX), Heat-Seal Pouch (125XX), and Heat-Seal Roll (124XX)	Self Seal Pouch (123XX), Heat-Seal Pouch (125XX), and Heat-Seal Roll (124XX)	Same
Design Features	Two films which are heat sealed together on three sides for individual pouches and on two sides for roll form pouches. A Chemical Indicator (CI) bar is printed onto the Tyvek® side of the pouch. For the self-seal pouch, the CI is printed onto back surface of the Tyvek®. For the heat-seal pouch and roll, the CI is printed onto the Tyvek®, but is encased in the seam of the pouch between the Tyvek® and transparent film.	Two films which are heat sealed together on three sides for individual pouches and on two sides for roll form pouches. A Chemical Indicator (CI) bar is printed onto the Tyvek® side of the pouch. For the self-seal pouch, the CI is printed onto back surface of the Tyvek®. For the heat-seal pouch and roll, the CI is printed onto the Tyvek®, but is encased in the seam of the pouch between the Tyvek® and transparent film.	Same
Chemical Indicator	STERRAD® indicator ink	STERRAD® indicator ink	Same
Chemical Indicator Device Design:	Chemical Indicator bar changes from red to yellow (or lighter) upon exposure to the sterilant, hydrogen peroxide	Chemical Indicator bar changes from red to yellow (or lighter) upon exposure to the sterilant, hydrogen peroxide	Same

5. SUMMARY OF NONCLINICAL TESTS

Performance testing was conducted to show that the Tyvek® Pouches and Rolls with STERRAD® Chemical Indicator perform as intended and, after completion of the sterilization process in the STERRAD® 100S, STERRAD®50, STERRAD®200, STERRAD®NX®, and STERRAD® 100NX® Sterilizers, maintain sterility until the pouch/roll is used. The testing also showed that the STERRAD® Chemical Indicator changes from red to yellow (or lighter) when exposed to hydrogen peroxide. Refer to Table 4 for the summary of performance testing.

Table 4: Pouch/Roll with Chemical Indicator Performance Tests

Study Type		Description	Results
Sterilant Penetration	Half-Cycle Efficacy	The sterilant penetrated through the “double pouch” configuration under the worst case half-cycle conditions and the sterility	Passed

Study Type		Description	Results
		assurance level (SAL) of 10^{-6} was demonstrated.	
	Chemical Indicator (CI) Functionality and Endpoint	The sterilant penetrated through the "double pouch" configuration and affected the CI color change to the endpoint color (from red to yellow or lighter) under the suboptimal conditions.	Passed
Package Integrity	Seal Strength	Seal strength performance characteristics were maintained for the manufactured seal and user made seal after STERRAD® processing.	Passed
	Microbial Barrier	The contents of pouches were sterile when the processed pouches were subjected to the microbial aerosol challenge test.	Passed
	Burst	Ability to withstand the internal pressurization was maintained after STERRAD® processing.	Passed
	Peel Open	Peel open characteristics of the Tyvek® Pouch/Roll were maintained after STERRAD® processing.	Passed
Maintenance of Package Integrity		Sterility was maintained in the Tyvek® Pouches/Rolls for 30 days after STERRAD® processing.	Passed
Material Compatibility		Seal strength test, microbial barrier properties, burst test, and peel open test were studied to demonstrate material compatibility characteristics of the Tyvek® Pouches/Rolls after STERRAD® processing.	Passed
End Point / Post Processing Color Stability		Tyvek® Pouches/Rolls, after STERRAD® processing, maintained the endpoint CI color reaction.	Passed
Shelf Life	Chemical Indicator (CI) Functionality	CI functionality of the processed Tyvek® Pouches/Rolls (CI color change from red to yellow or lighter) was verified at the end of shelf life.	Passed
	Seal Strength	Seal strength of the processed Tyvek® Pouches/Rolls was verified at the end of shelf life.	Passed
Biocompatibility		*In vivo* testing showed that the pouch samples, after STERRAD® processing, met the acceptance criteria per ISO 10993-11 and 10993-10.	Passed

6. OVERALL PERFORMANCE CONCLUSIONS

The nonclinical studies demonstrate that the Tyvek® Pouch/Roll with STERRAD® Chemical Indicator performs as intended as a sterilization packaging system of medical devices that are being terminally sterilized in STERRAD® Sterilization Systems. The Chemical Indicator performs as intended for differentiating processed from unprocessed packages in the STERRAD® Sterilization Systems. These studies also show that the proposed pouches have the same intended use and met the same criteria as the predicate device (K112087) and are substantially equivalent.

Tyvek® is a registered trademark of DuPont