October 27, 2017

Andersen Sterilizers, Inc.
William Andersen
President
3154 Caroline Drive
Haw River, North Carolina 27258

Re: K170429
Trade/Device Name: Tyvek Sterilization Pouches with Chevron Seal
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: September 28, 2017
Received: October 6, 2017

Dear William Andersen:

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 (DICE) 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 (DICE) 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 on last page.

510(k) Number *(if known)*
K170429

Device Name
Tyvek® Sterilization Pouches with Chevron Seal

Indications for Use *(Describe)*

Tyvek Sterilization Pouches with Chevron Seal are intended to enclose medical devices that are to be sterilized in a single pouch configuration at a healthcare facility. They are used in the 12 hour sterilization cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer. Critical process parameters for the cycle are summarized in Table 1.

Table 1. Critical sterilization cycle parameters in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

EO Amount	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
17.6 g ± 5%	20-29°C	35-90%	12 hours	14 hours

The product codes for Tyvek Sterilization Pouches are listed in Table 2.

Table 2. Product codes for Tyvek Sterilization Pouches

Product Type	Self-Seal, Heat Seal, Tubing
Product Codes	TLP-030, TLP-031, TLP-033, TLP-058, TLP-059

The 12 hour cycle in the Anprolene AN75 Ethylene Oxide Gas Sterilizer has been validated to sterilize a load of up to 24 lbs of metal surgical instruments, 3 lbs of fabric, or 3.5 lbs of plastic devices (combined weight of pouched devices and tray). Sterility was maintained for at least 3 months after processing in an Anprolene AN75 sterilizer.

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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K170429 510(k) Summary

5.1 Applicant's Name and Address

Andersen Sterilizers, Inc.
Establishment Registration Number 3004634710
3154 Caroline Drive
Haw River, NC 27258

5.2 Contact Person

William K. Andersen, BE, MD, FAAOS
President
Phone: 336-376-8622, Fax: 336-376-5428

5.3 Date of Preparation

September 28, 2017

5.4 Device

Proprietary Name	Tyvek® Sterilization Pouches with Chevron Seal
Common Name	Sterilization Pouch
Classification	Class II (21 CFR 880.6850)
Product Code	FRG

5.5 Predicate Device

Device Name	Tyvek Sterilization Pouches with Chevron Seal
510(k) number	K152058
Manufacturer	Amcor Flexibles, Inc.

The predicate Tyvek Sterilization Pouches with Chevron Seal (K152058) are approved as an accessory for use in the EOGas 4® Ethylene Oxide Gas Sterilization System manufactured by Andersen Sterilizers, Inc.

This 510(k) submission modifies the indications for use of the predicate device in order to include Tyvek Sterilization Pouches with Chevron Seal as an accessory for use in the Anprolene® AN75 Ethylene Oxide Sterilization System manufactured by Andersen Sterilizers, Inc. No modifications were made to the manufacturing method, technology, or intended use.

5.6 Device Description

Tyvek Sterilization Pouches with Chevron Seal are constructed from an uncoated Tyvek backing of fine, continuous, high-density polyethylene fibers, with front material consisting of a clear, laminated polyethylene terephthalate / low density polyethylene (LDPE) or LDPE-ethylene-vinylacetate copolymer film. The pouches are used to enclose medical devices that are to be sterilized by a healthcare provider in the 12 hour sterilization cycle at 20-29°C in an Anprolene AN75 Ethylene Oxide Gas Sterilizer. Following manufacturer's instructions, devices are inserted into Tyvek Sterilization Pouches and sealed. The self-seal pouch permits sealing of the pouch without heat-sealing equipment, whereas the heat-sealable pouches must be heat sealed

prior to the cycle. Andersen Sterilizers' AN85/AN86 EO Indicators, when placed on the outside of the sterilization pouches, indicate EO exposure and offer a convenient way to differentiate pouches that have been processed in EO sterilization cycles from unprocessed units. The color of the AN85/AN86 EO Indicators changes from yellow-green to blue after exposure to EO. After completion of the sterilization process, the pouches maintain sterility of the enclosed medical devices for at least 3 months (90 days).

5.7 Indications for Use

Tyvek Sterilization Pouches with Chevron Seal are intended to enclose medical devices that are to be sterilized in a single pouch configuration at a healthcare facility. They are used in the 12 hour sterilization cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer. Critical process parameters for the cycle are summarized in **Table 5-1**.

Table 5-1. Critical parameters for the 12 hour cycle in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	**Temperature**	**Relative Humidity**	**Ethylene Oxide Exposure Time**	**Total Cycle Time**
17.6 g ± 5%	20-29°C	35-90%	12 hours	14 hours

The product codes for Tyvek Sterilization Pouches are listed in **Table 5-2**.

Table 5-2. Product codes for Tyvek Sterilization Pouches

Product Type	Self-Seal, Heat Seal, Tubing
Product Codes	TLP-030, TLP-031, TLP-033, TLP-058, TLP-059

The 12 hour cycle in the Anprolene AN75 Ethylene Oxide Gas Sterilizer has been validated to sterilize a load of up to 24 lbs of metal surgical instruments, 3 lbs of fabric, or 3.5 lbs of plastic devices (combined weight of pouched devices and tray). Sterility was maintained for at least 3 months after processing in an Anprolene AN75 sterilizer.

5.8 Device Comparison

The technological characteristics of Tyvek Sterilization Pouches with Chevron Seal are identical to the predicate device - both are intended for the same use, use the same technology, and are designed in the same way.

The subject Tyvek Sterilization Pouches with Chevron Seal differ from the predicate device only in the indicated sterilization cycle. The difference raises no issues related to safety or effectiveness of the subject device in the cycle. A comparison between the devices is listed in **Table 5-3**.

Table 5-3. Device Comparison

Elements	Predicate Device: Tyvek Sterilization Pouches (K152058)	Subject Device: Tyvek Sterilization Pouches (K170429)
Intended Use	To enclose medical devices, allow sterilization of the enclosed devices, and maintain sterility of the enclosed devices	Identical
Indications for Use	Tyvek Sterilization Pouches with Chevron Seal are intended to enclose medical devices that are to be sterilized in a single pouch configuration at a healthcare facility. They are used in the 3 hour sterilization cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.	Tyvek Sterilization Pouches with Chevron Seal are used to enclose medical devices that are to be sterilized in a single pouch configuration at a healthcare facility. They are used in the 12 hour sterilization cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer.
Design	Adhesive laminated film is a clear, high strength material; Uncoated Tyvek is compatible with EO sterilization, resistant to microbial penetration, and resistant to puncture	Identical
Pouch Types	Self-seal pouch; Heat seal pouch; Heat seal tubing	Identical
Device Construction	Self-seal and heat seal pouches: front and back materials are heat sealed together on three sides; fourth side (end) remains open for filling; end is sealed by heat (heat seal pouches) or by removing protective liner strip, folding along the pre-fold, and pressing to the film (self-seal pouches). Heat seal tubing: front and back materials are heat sealed together on two sides; two ends are open for selecting size and filling; ends are sealed by heat.	Identical
Materials	Clear laminated PET/LDPE or LDPE-EVA film (front) and uncoated HDPE Tyvek (back)	Identical
Configuration	Single pouch configuration	Identical
Shelf Life	5 years from date of manufacture	Identical
Biocompatibility	Materials and biological evaluations (Agar Diffusion Test, Cytotoxicity Test) meet ISO 11607-1 requirements	Identical
Maintenance of Sterility	Sterility is maintained for at least 3 months after processing in an EOGas 4 sterilizer	Sterility is maintained for at least 3 months after processing in an Anprolene AN75 sterilizer
Aeration Time	≥ 6 hours	No additional time other than the 2 hr mandatory ventilation
Package Integrity	Seal strength, microbial barrier, burst, and peel open characteristics meet ISO and ASTM requirements	Identical

5.9 Performance Testing

Performance testing was conducted to demonstrate that Tyvek Sterilization Pouches with Chevron Seal perform as intended to allow sterilization of the enclosed medical devices. Sterilization efficacy testing demonstrated a 12-Log reduction and a sterility assurance level of 10^{-6} using the half dose validation method under worst-case conditions. Tyvek Sterilization Pouches with Chevron Seal also maintain sterility of the enclosed devices as intended. Shelf life studies demonstrated after completion of the Anprolene AN75 sterilization process, sterility is maintained for at least 3 months. The performance of Tyvek Sterilization pouches is summarized in **Table 5-4**.

Table 5-4. Summary of bench tests performed to demonstrate safety and effectiveness of Tyvek Sterilization Pouches

Test	Description	Results
Compliance to ISO 11607-1		
Package Integrity	Seal strength performance characteristics were maintained for the manufactured seal. Microbial Barrier: the contents of pouches were sterile when the processed pouches were subjected to the microbial aerosol challenge test. Burst: ability to withstand the internal pressurization was maintained. Peel open characteristics were maintained.	Meet ISO and ASTM requirements
Material Compatibility	Seal strength test, microbial barrier properties, burst test, and peel open test were studied to demonstrate material compatibility characteristics of the Tyvek Sterilization Pouches	Pass
Biocompatibility	Not direct patient-contacting devices; Materials are non-toxic, FDA compliant, and meet ISO 11607-1 requirements; Biological and residual evaluations meet acceptable criteria; Provides reasonable assurance for safety	Pass
Shelf Life	Physical properties and microbial barrier of the processed Tyvek Pouches was verified at the end of shelf life of 5 years; Stability demonstrates reasonable assurance for effectiveness	Pass
Performance in the Anprolene AN75 Cycle		
Sterilant Penetration	EO penetrated the pouch under worst-case half-dose conditions or an extreme biological challenge scenario, and inactivated 6-Log biological indicators	Allow a SAL of 10^{-6} for the sterilization cycle
Maintenance of Package Sterility	Sterility was maintained for at least 3 months after processing in an Anprolene AN75 sterilizer.	Pass

5.10 Conclusion

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, the subject Tyvek Sterilization Pouches with Chevron Seal, indicated for use in the Anprolene AN75 sterilization system, are substantially equivalent to the predicate devices, Tyvek Sterilization Pouches with Chevron Seal (K152058), indicated for use in the EOGas 4 sterilization system.