November 12, 2020

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

Re: K200336
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: October 8, 2020
Received: October 13, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CAPT Elizabeth Claverie, MS
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200336

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 3-hour and 6-hour gas exposures at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.

Critical process parameters for the cycle are summarized in Table 1.

Table 1. Critical sterilization cycle parameters in the EOGas 4 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
17.6 g ± 5%	50°C ± 3°C	35-70%	3 hours	3.5 hours
			6 hours	7 hours

The EOGas 4 Ethylene Oxide Gas Sterilizer 3-hour gas exposure is used for surface sterilization of medical devices, including instruments with diffusion-restricted spaces (hinges or mated surfaces), as well as for the sterilization of endoscopes working length shorter than 1100 mm as specified in the sterilizer labeling.

The EOGas 4 Ethylene Oxide Gas Sterilizer 6-hour gas exposure is used for sterilization of duodenoscopes and colonoscopes with working length longer than 1100 mm as specified in the sterilizer labeling.

Table 2. Load and material types validated in the EOGas 4 Ethylene Oxide Gas Sterilizer

Device Type	Maximum Load	Device Examples	Required Aeration
3-Hour EO Exposure, EOGas 4 SteriTest PCD (Blue Purge Probe)			
Metal	24 lbs (11 kg)	Surgical instruments, delicate sharps, including those with hinges and mated surfaces	No additional aeration required; Follow pouch or wrap manufacturer's instructions (Example: Tyvek pouches require ≥ 6 hours at 50°C)
Plastic	7.0 lbs (3.2 kg)	Reusable power cords, trocars, and similar devices	24 hours at 50°C; Follow manufacturer's instructions
Fabric	6.1 lbs (2.8 kg)	Reusable cloth gowns, towels, and similar devices	
≤ 1100 mm Working Lumen Length Endoscopes	One (1) ≥ 2.0 mm ID biopsy channel ≤ 1100 mm working length	Gastrovideoscopes, gastrointestinal videoscopes, and similar devices	8 hours at 50°C; Follow manufacturer's instructions
	Four (4) ≥ 1.2 mm ID biopsy channel ≤ 700 mm working length	Bronchoscopes, bronchovideoscopes, cystoscopes, ureteroscopes, choledocoscopes, and similar devices	
6-Hour EO Exposure, EOGas 4 Endo-SteriTest PCD (Gold Purge Probe)			
>1100 mm Working Lumen Length Endoscopes	Two (2) Duodenoscopes* ≥ 2.0 mm ID biopsy channel ≤ 1250 mm working length ≥ 1.2 mm ID, ≤ 3530 mm maximum length of any channel	Olympus TJF-Q180V, Olympus TJF-Q160VF , Olympus TJF-Q190V, Olympus PJF-160, Fujifilm ED-530XT, Pentax ED34-i10T2, Pentax ED-3490TK	6 hours at 50°C for Olympus and Pentax endoscopes in Sterisheet 8 hours at 50°C for Fujifilm endoscopes in Sterisheet
	Two (2) Colonoscopes* ≥ 3.7 mm ID biopsy channel ≤ 1700 mm working length ≥ 1.2 mm ID, ≤ 3530 mm maximum length of any channel	Olympus CF-Q180AL, Fujifilm EC-600HL, Pentax EC-3490Li	Follow manufacturer's instructions

* One (1) duodenoscope may also be paired with one (1) colonoscope

After completion of the sterilization process, the pouches maintain sterility of the enclosed medical devices for 6 months.

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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510(k) Summary
K200336

Applicant's Name and Address

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

Contact Person

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

Date of Preparation

February 3, 2020

Device

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

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**) were cleared as an accessory for use in 3-hour gas exposures in the EOGas 4 Ethylene Oxide Gas Sterilization System manufactured by Andersen Sterilizers, Inc.

The 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 6-hour gas exposures in the EOGas 4 Ethylene Oxide Sterilization System manufactured by Andersen Sterilizers, Inc. No modifications were made to the manufacturing method, technology, or intended use.

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-vinyl acetate copolymer film. The pouches are used to enclose medical devices that are to be sterilized by a healthcare provider in 3-hour and 6-hour gas exposures at 50°C in the EOGas 4 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 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 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 6 months.

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 3-hour and 6-hour gas exposures at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer. Critical process parameters for the cycle are summarized in **Table 5-1**.

Table 5-1. Critical sterilization cycle parameters for EOGas 4 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	Temperature	Relative Humidity	Ethylene Oxide Exposure Time	Total Cycle Time
17.6 g ± 5%	50°C ± 3°C	35-90%	3 hours	3.5 hours
			6 hours	7 hours

The EOGas 4 Ethylene Oxide Gas Sterilizer 3-hour gas exposure is used for surface sterilization of medical devices, including instruments with diffusion-restricted spaces (hinges or mated surfaces), as well as for the sterilization of endoscopes working length shorter than 1100 mm as specified in the sterilizer labeling.

The EOGas 4 Ethylene Oxide Gas Sterilizer 6-hour gas exposure is used for sterilization of duodenoscopes and colonoscopes with working length longer than 1100 mm as specified in the sterilizer labeling.

Table 5- 2. Load and material types validated in the EOGas 4 Ethylene Oxide Gas Sterilizer

Device Type	Maximum Load	Device Examples	Required Aeration
3-Hour EO Exposure, EOGas 4 SteriTest PCD (Blue Purge Probe)			
Metal	24 lbs (11 kg)	Surgical instruments, delicate sharps, including those with hinges and mated surfaces	No additional aeration required; Follow pouch or wrap manufacturer's instructions (Example: Tyvek pouches require ≥ 6 hours at 50°C)
Plastic	7.0 lbs (3.2 kg)	Reusable power cords, trocars, and similar devices	24 hours at 50°C; Follow manufacturer's instructions
Fabric	6.1 lbs (2.8 kg)	Reusable cloth gowns, towels, and similar devices	
≤ 1100 mm Working Lumen Length Endoscopes	One (1) ≥ 2.0 mm ID biopsy channel ≤ 1100 mm working length	Gastrovideoscopes, gastrointestinal videoscopes, and similar devices	8 hours at 50°C if in Sterisheet; Follow manufacturer's instructions
	Four (4) ≥ 1.2 mm ID biopsy channel ≤ 700 mm working length	Bronchoscopes, bronchovideoscopes, cystoscopes, ureteroscopes, choledocoscopes, and similar devices	
6-Hour EO Exposure, EOGas 4 Endo-SteriTest PCD (Gold Purge Probe)			
>1100 mm Working Lumen Length Endoscopes	Two (2) Duodenoscopes* ≥ 2.0 mm ID biopsy channel ≤ 1250 mm working length ≥ 1.2 mm ID, ≤ 3530 mm maximum length of any channel	Olympus TJF-Q180V, Olympus TJF-Q160VF, Olympus TJF-Q190V, Olympus PJF-160, Fujifilm ED-530XT, Pentax ED34-i10T2 Pentax ED-3490TK	6 hours at 50°C for Olympus and Pentax endoscopes in Sterisheet; 8 hours at 50°C for Fujifilm endoscopes in Sterisheet; Follow manufacturer's instructions
	Two (2) Colonoscopes* ≥ 3.7 mm ID biopsy channel ≤ 1700 mm working length ≥ 1.2 mm ID, ≤ 3530 mm maximum length of any channel	Olympus CF-Q180AL, Fujifilm EC-600HL, Pentax EC-3490Li	
	* One (1) duodenoscope may also be paired with one (1) colonoscope		

After completion of the sterilization process, the pouches maintain sterility of the enclosed medical devices for 6 months.

Technological Characteristics

The technological characteristics of Tyvek Sterilization Pouches with Chevron Seal are identical to the predicate device (**K152058**) - 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 cycles. 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 (K200336)
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 3-hour gas exposures at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.	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 3-hour and 6-hour gas exposures at 50°C in the EOGas 4 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 3 months after processing in the EOGas 4 Ethylene Oxide Gas Sterilizer	Sterility is maintained for 6 months after processing in the EOGas 4 Ethylene Oxide Gas Sterilizer
Aeration Time	≥ 6 hours	≥ 6 hours
Package Integrity	Seal strength, microbial barrier, burst, and peel open characteristics meet ISO and ASTM requirements	Identical

Summary of Non-Clinical Testing

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 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 EOGas 4 sterilization process, sterility is maintained for 6 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 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 6-hour Gas exposure in the EOGas 4 Ethylene Oxide Gas Sterilizer		
Sterilant Penetration	EO penetrated the pouch under worst-case half-dose conditions or a worst-case biological challenge, and inactivated 6-Log biological indicators	Confirmed SAL of 10^{-6} in 6-hour gas exposures
Maintenance of Package Sterility	Sterility was maintained for 6 months after processing in 6-hour gas exposures in the EOGas 4 Ethylene Oxide Gas Sterilizer.	Pass

Conclusion

The conclusions drawn from the nonclinical test demonstrate that the Tyvek Sterilization Pouches with Chevron Seal is as safe, as effective, and performs as well as or better than the legally marketed Tyvek Sterilization Pouches with Chevron Seal (**K152058**)