November 12, 2020

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

Re: K200335
Trade/Device Name: Sterisheet Sterilization Wrap
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)*
K200335

Device Name
Sterisheet Sterilization Wrap

Indications for Use *(Describe)*

Sterisheet Sterilization Wraps are single use non-woven sterilization wraps intended to enclose medical devices that are to be sterilized 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 EOGas 4 sterilization process, sterility is maintained for 6 months in Sterisheet sterilization wraps.

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
K200335

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

October 8, 2020

Device

Proprietary Name	Sterisheet Sterilization Wrap
Common Name	Sterilization Wrap
Classification	Class II (21 CFR 880.6850)
Product Code	FRG

Predicate Device

Device Name	Sterisheet Sterilization Wrap
510(k) number	**K152291**
Manufacturer	Arjowiggins Medical Inc.

The predicate Sterisheet Sterilization Wrap (**K152291**) was cleared 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 it as an accessory for 6-hour gas exposures in the EOGas 4 Ethylene Oxide Gas Sterilization system manufactured by Andersen Sterilizers, Inc. No modifications were made to the manufacturing method, technology, or intended use.

Device Description

Sterisheet Sterilization Wraps are single use, non-sterile sterilization wraps constructed from cellulose, synthetic fibers (polypropylene), and synthetic binders, with the addition of pigmentation. They 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. Devices must be wrapped following manufacturer's instructions. After completion of the sterilization process, Sterisheet Sterilization Wraps maintain sterility of the enclosed medical devices for 6 month.

AN85 EO Indicators, when placed on the outside of the sterilization wraps, may be used to secure the wrapping material on the devices and to indicate ethylene oxide exposure, offering a convenient way to verify processing in the sterilization cycle. The color of the AN85 EO Indicators changes from yellow-green to blue after exposure to ethylene oxide.

Indications for Use

Sterisheet Sterilization Wraps are single use non-woven sterilization wraps intended to enclose medical devices that are to be sterilized 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 in the 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 EOGas 4 sterilization process, sterility is maintained for 6 months in Sterisheet sterilization wraps.

Technological Characteristics Comparison

The technological characteristics of the subject Sterisheet Sterilization Wraps are identical to the predicate device (**K152291**) - both are intended for the same use, use the same technology, and are designed in the same way.

The only difference between the subject Sterisheet Sterilization Wrap and the predicate device is the sterilization cycle for which the subject Sterisheet Sterilization Wrap is indicated.. A comparison between the devices is listed in **Table 5-3**.

Table 5-3. Device Comparison

Elements	Predicate Sterisheet Sterilization Wraps (K152291)	Subject Sterisheet Sterilization Wraps (K200335)	Remarks
Manufacturer	Arjowiggins Healthcare	Arjowiggins Healthcare	Same
Intended Use	To enclose medical devices, allow sterilization of the enclosed devices, and maintain sterility of the enclosed devices	Identical	Identical
Indications for Use	Sterisheet Sterilization Wraps are single use non-woven sterilization wraps intended to enclose medical devices that are to be sterilized at a healthcare facility. They are used in 3-hour gas exposures at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.	Sterisheet Sterilization Wraps are single use non-woven sterilization wraps intended to enclose medical devices that are to be sterilized 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.	Similar
Sterilization Cycle Time	3-hour gas exposure	3-hour and 6-hour gas exposure	Different
Materials	Cellulose, synthetic fibers (polypropylene), and synthetic binders	Identical	Identical
Design	Cellulose allows EO to pass through the wrap but prevents microorganisms from crossing through the wrap, providing a microbial barrier for the wrapped devices after sterilization; Synthetic fibers increase mechanical resistance; Synthetic binders enhance drapeability, strength, softness, and fluid repellency	Identical	Identical
Wrap Shape	Square or rectangular	Identical	Identical
Configuration in Load	Double sequential envelope wrap is recommended	Identical	Identical
Shelf Life	5 years from date of manufacture	Identical	Identical

Aeration Time	≥ 6 hours	≥ 6 hours	Similar
Sterility Maintenance	3 months after cycle	6 months after cycle	Similar

Summary of Non-Clinical Testing

Performance Testing

Sterisheet Sterilization Wraps conform to all applicable requirements for packaging for terminally sterilized medical devices for EO sterilization, based on ISO 11607-1. Performance testing was conducted to show that Sterisheet Sterilization Wraps perform as intended to allow sterilization and maintain sterility of the enclosed medical device. Sterilization efficacy testing demonstrated a sterility assurance level of 10^{-6} using the half dose validation method under worst-case conditions. Shelf life studies demonstrated after completion of the EOGas 4 sterilization process, sterility is maintained for 6 months. The performance of Sterisheet Sterilization Wraps is summarized in **Table 5-4.**

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

Test	Purpose	Acceptance Criteria	Results
Compliance to ISO 11607-1			
Physical and Chemical Properties	To evaluate the package integrity after EO sterilization	Various standards for various properties. For example, ISO 536 for Substance, ISO 5636-3 for Permeability, EN 868-2 for Fluorescence and Water repellency	There was no effect on the physical and chemical properties after EO sterilization.
Bacterial Filtration Efficiency and Germ Proofness dry and wet challenge test	To demonstrate that Sterisheet provide a microbial barrier property	Bacterial Filtration Efficiency (ASTM F2101) Germ Proofness dry and wet challenge test (DIN 58953-6)	Sterisheet passed all tests and were effective for sterility assurance pre- and post-EO sterilization.
Material Compatibility	To demonstrate Sterisheet is suitable for use in EO sterilization processes and the associated cycle parameters	The physical, chemical, and microbial barrier properties of Sterisheet are compatible for intended use in EO sterilization per ISO 10993 and USP	The ability of the wraps to act as a microbial barrier was unaffected, and the contents of the packs remained sterile after EO sterilization

Test	Purpose	Acceptance Criteria	Results
Biocompatibility	To demonstrate that Sterisheet provides reasonable assurance for safety	Biological evaluation (MEM Elution, Sensitization and Irritation Test) per ISO 10993 and USP	Not direct patient-contacting devices; Biological evaluation Showed that Sterisheet met all accepted performance criteria for non-toxicity. No pigment leaches out of Sterisheet during 6-hour EO exposures. With an additional 6-hour aeration, the residual EO detected in Sterisheet met ISO 10993-7 requirements.
Shelf Life	To evaluate the physical, chemical, and microbial barrier of the processed Sterisheet at the end of the clamed shelf life	Stability demonstrates reasonable assurance for effectiveness	The physical, chemical, and microbial barrier properties of the wraps were verified at the end of 5 years and met specifications.
Performance in the 6-hour Gas exposure in the EOGas 4 Ethylene Oxide Gas Sterilizer			
Sterilant Penetration	To demonstrate Sterisheet allow sterilization of the wrapped devices in half dose, full dose, simulated-use and in-use testing	Inactivation of 6-Log biological indicators at the worst-case location in the endoscope load wrapped in the Sterisheet for all the testing performed	Data demonstrate that Sterisheet Sterilization Wraps allow penetration of EO and sterilization of the enclosed devices.
Maintenance of Package Sterility	To demonstrate Sterisheet maintain sterility of the enclosed medical device	The sterilized devices wrapped in Sterisheet remain sterile	Sterility was maintained for 6 months after processing in Sterisheet wrapped endoscopes.

Conclusion

The conclusion drawn from the nonclinical tests demonstrates that the subject device in 510(K) submission **K200335**, the Sterisheet Sterilization Wrap is as safe, as effective, and performs as well as or better than the legally marketed predicate device cleared under **K152291.**