November 1, 2017

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

Re: K170437
Trade/Device Name: Sterisheet Sterilization Wrap
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)*

K170437

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 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 below 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 code for Sterisheet Sterilization Wraps is listed in Table 2.

Table 2. Product code for Sterisheet Sterilization Wraps

Product Designation	Sterisheet S88 Blue
Product Code	0129
Sizes	18”x18’’, 20”x20”, 24”x24”, 30”x30”, 36”x36”, 40”x40”, 45”x45”, 48”x48”, 54”x54”, and 54”x72”

The 12 hour cycle in the Anprolene 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 wrapped devices and tray). Sterility was maintained for at least 3 months after processing in an Anprolene sterilization cycle.

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 K170437

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

October 20, 2017

5.4 Device

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

5.5 Predicate Device

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

The predicate Sterisheet Sterilization Wrap (K152291) is approved 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 it as a component in the Anprolene® AN75 Ethylene Oxide Gas Sterilization system manufactured by Andersen Sterilizers, Inc. No modifications were made to the manufacturing method, technology, or intended use.

5.6 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 the 12 hour sterilization cycle at 20-29°C in an Anprolene AN75 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 at least 3 months.

AN85/AN86 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/AN86 EO Indicators changes from yellow-green to blue after exposure to ethylene oxide.

5.7 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 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 sterilization cycle parameters 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 code for Sterisheet Sterilization Wraps is listed in **Table 5-2**.

Table 5-2. Product code for Sterisheet Sterilization Wraps

Product Designation	Sterisheet S88 Blue
Product Code	0129
Sizes	18”x18’’, 20”x20”, 24”x24”, 30”x30”, 36”x36”, 40”x40”, 45”x45”, 48”x48”, 54”x54”, and 54”x72”

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 wrapped devices and tray). Sterility was maintained for at least 3 months after processing in an Anprolene AN75 sterilization cycle.

5.8 Device 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. The

difference raises no issues related to safety or effectiveness of the subject device in the sterilization cycle. 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
Manufacturer	Arjowiggins Healthcare	Arjowiggins Healthcare
Intended Use	To enclose medical devices, allow sterilization of the enclosed devices, and maintain sterility of the enclosed devices	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 the 3 hour sterilization cycle 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 the 12 hour sterilization cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer.
Materials	Cellulose, synthetic fibers (polypropylene), and synthetic binders	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
Wrap Shape	Square or rectangular	Identical
Configuration in Load	Double sequential envelope wrap is recommended	Identical
Shelf Life	5 years from date of manufacture	Identical
Aeration Time	≥ 6 hours	≥ 6 hours

5.9 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 Anprolene AN75 sterilization process, sterility is maintained for at least 3 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	Description	Results
Compliance to ISO 11607-1		
Package Integrity	Porous material providing a microbial barrier; Physical and chemical properties are maintained	Meets requirements
Material Compatibility	Compatibility with respect to forming and sealing process-suitable folding and drapeability; Suitable for use in EO sterilization processes	Meets requirements
Biocompatibility	Not direct patient-contacting devices; Materials are non-toxic and meet ISO 11607-1 requirements; Biological evaluation meets acceptable criteria; Bio-burden control; Provides reasonable assurance for safety	Pass
Shelf Life	Physical properties and microbial barrier of the processed Sterisheet Sterilization Wraps were verified at the end of the clamed shelf life of 5 years; Stability demonstrates reasonable assurance for effectiveness	Pass
Performance in the Anprolene AN75 Cycle		
Sterilant Penetration	EO penetrated the wraps under worst-case half-dose conditions or an extreme biological challenge scenario, and inactivated 6-Log biological indicators	Allow a sterility assurance level 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, and nonclinical tests performed, the subject device Sterisheet Sterilization Wrap (K170437) is as safe and effective as the legally marketed predicate device, Sterisheet Sterilization Wrap (K152291) intended for used in the EOGas4 sterilization system.