DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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December 17, 2015

Andersen Sterilizers, Inc.
William K. Andersen, B.E., M.D.
President
3154 Caroline Dr.
Haw River, NC 27258

Re: K152291
Trade/Device Name: Sterisheet® Sterilization Wrap
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: November 16, 2015
Received: November 19, 2015

Dear Dr. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
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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)*
K152291

Device Name
Sterisheet® Sterilization Wrap

Indications for Use *(Describe)*
The 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.

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

Table 1. Critical parameters for the 3 hour cycle in the EOGas 4 Ethylene Oxide Gas Sterilizer

EO Amount	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
17.6 g ± 5%	50°C ± 3°C	35-90%	3 hours	3.5 hours

The product code for the Sterisheet Sterilization Wraps is listed in Table 2.

Table 2. Product code for the Sterisheet Sterilization Wraps

Product Designation	Sterisheet S88 Blue
Product Code	0129

Maximum loads of specific materials and devices that have been validated are listed in Table 3. All validated maximum loads were processed without additional devices in the sterilizer. Sterility was maintained for at least 3 month after processing in an EOGas 4 sterilizer.

Table 3. Load and material types validated in the EOGas 4 Ethylene Oxide Gas Sterilizer

Device Type	Maximum Load	Device Examples	Required Aeration
Metal	24 lbs (11 kg)	Surgical instruments, delicate sharps, including those with hinges and mated surfaces	Metal instruments do not absorb EO; Follow pouch or wrap manufacturer's instructions (Example: Tyvek® pouches and Sterisheet® wrap require ≥ 6 hours at 50°C).
Plastic	7.0 lbs (3.2 kg)	Reusable power cords, trocars	24 hours at 50°C;
Fabric	6.1 lbs (2.8 kg)	Reusable cloth gowns, towels	Follow manufacturer's instructions
Single-lumen Endoscope(s)	One (1) ≥ 2.0mm ID ≤ 1100mm length; No additional devices	Gastrovideoscopes, gastrointestinal videoscopes	12 hours at 50°C; Follow manufacturer's instructions
	Four (4) ≥ 1.2 mm ID ≤ 700 mm length; No additional devices	Bronchoscopes, bronchovideoscopes, cystoscopes, ureteroscopes, choledocoscopes	

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)*

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510(k) Summary

5.1 Applicant's Name and Address

Andersen Sterilizers, Inc.
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

November 16, 2015

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	K931202
Manufacturer	Arjowiggins Medical Inc.

This 510(k) submission modifies the indications for use of the predicate device in order to include it as a component in the EOGas 4® ethylene oxide sterilization system. No modifications were made to the technology or intended use.

5.6 Device Description

The 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 3 hour sterilization cycle at 50°C in an EOGas 4 Ethylene Oxide Gas Sterilizer. Devices are wrapped following manufacturer's instructions. After completion of the sterilization process, the Sterisheet Sterilization Wraps maintain sterility of the enclosed medical devices for at least 3 month.

The 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

The 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. Critical process parameters for the cycle are summarized in **Table 5-1**.

Table 5-1. Critical parameters for the 3 hour cycle 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

The product code for the Sterisheet Sterilization Wraps is listed in **Table 5-2**.

Table 5-2. Product code for the Sterisheet Sterilization Wraps

Product Designation	Sterisheet S88 Blue
Product Code	0129

Maximum loads of specific materials and devices that have been validated are listed in **Table 5-3**. All validated maximum loads were processed without additional devices in the sterilizer. Sterility was maintained for at least 3 month after processing in an EOGas 4 sterilizer.

Table 5-3. Load and material types validated in the EOGas 4 Ethylene Oxide Gas Sterilizer

Device Type	Maximum Load	Device Examples	Required Aeration
Metal	24 lbs (11 kg)	Surgical instruments, delicate sharps, including those with hinges and mated surfaces	Metal instruments do not absorb EO; Follow pouch or wrap manufacturer's instructions for aeration requirements (Examples: Tyvek® pouches and Sterisheet® wrap require ≥ 6 hours aeration at 50°C).
Plastic	7.0 lbs (3.2 kg)	Reusable power cords, trocars	24 hours at 50°C; Follow manufacturer's instructions
Fabric	6.1 lbs (2.8 kg)	Reusable cloth gowns, towels	
Single-lumen Endoscope(s)	One (1) ≥ 2.0 mm internal diameter ≤ 1100 mm length; No additional devices	Gastrovideoscopes, gastrointestinal videoscopes	12 hours at 50°C; Follow manufacturer's instructions
	Four (4) ≥ 1.2 mm internal diameter ≤ 700 mm length; No additional devices	Bronchoscopes, bronchovideoscopes, cystoscopes, ureteroscopes, choledocoscopes	

5.8 Device Comparison

The technological characteristics of the Sterisheet Sterilization Wraps 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 Sterisheet Sterilization Wraps differ from the predicate device in the sterilization cycle used. 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 Device: Sterisheet Sterilization Wraps (K931202)**	**Subject Device: 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	To be used in ethylene oxide sterilization systems	To be used in the 3 hour cycle at 50°C in an EOGas 4 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; Synthetic fibers increase mechanical resistance; Synthetic binders enhance drape ability, 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

5.9 Performance Testing

The 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 the 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 overkill method and half cycle or half dose validation methods under worst case conditions. Shelf life studies demonstrated after completion of the sterilization process, sterility is maintained for at least 3 month. The performance of the Sterisheet Sterilization Wraps is summarized in **Table 5-4**.

Table 5-4. Summary of bench tests performed to demonstrate safety and effectiveness of the 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	Meet requirements
Material Compatibility	Compatibility with respect to forming and sealing processes-suitable folding and drape ability; Suitability for use in EO sterilization processes and cycle parameters	Meet 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 EOGas 4 Cycle		
Sterilant Penetration	The sterilant penetrated the pouch 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 Integrity	Sterility was maintained for at least 3 month after processing in an EOGas 4 sterilizer.	Pass

Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, the subject Sterisheet Sterilization Wrap is substantially equivalent and is as safe and as effective as the legally marketed predicate device.