U.S. FOOD & DRUG ADMINISTRATION

October 31, 2017

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

Re: K170432 ✓
Trade/Device Name: Anprolene AN75 Ethylene Oxide Gas Sterilizer
Regulation Number: 21 CFR 880.6860
Regulation Name: Ethylene Oxide Gas Sterilizer
Regulatory Class: Class II
Product Code: FLF
Dated: October 4, 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)*
K170432

Device Name
Anprolene AN75 Ethylene Oxide Gas Sterilizer

Indications for Use *(Describe)*

The Anprolene AN75 Ethylene Oxide Gas Sterilizer is intended for use in hospitals and other human healthcare settings. It is designed to sterilize reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation.

The 12 hour cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer is for surface sterilization of medical devices, including mated surfaces. The 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 (68-84°F)	35-70%	12 hours	14 hours

Maximum loads of specific materials and devices that have been validated are listed in Table 2. All validated maximum loads were processed without additional devices in the sterilizer.

Table 2. Load and material types validated in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

Device Type	Maximum Load	Device Examples	Required Aeration
Metal	24 lbs (11 kg)	Delicate sharps and surgical instruments, including those with hinges and mated surfaces	Metal instruments do not absorb EO; Follow pouch or wrap manufacturer's instructions (Example: Sterisheet® wraps require ≥ 6 hours at 20-29°C).
Plastic	3.5 lbs (1.6 kg)	Reusable power cords, trocars	Follow manufacturer's instructions; 24 hours at 20-29°C
Fabric	3.0 lbs (1.4 kg)	Reusable cloth gowns, towels	Follow manufacturer's instructions; 24 hours at 20-29°C.

Reusable medical devices must be aerated following the instructions of device manufacturers and packaging material manufacturers, then released for use after sterilization based on successful inactivation of an EZTest®- Gas Biological Indicator in the Anprolene SteriTest process challenge device.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

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 27, 2017

Device

Proprietary Name	Anprolene AN75 Ethylene Oxide Gas Sterilizer
Common Name	Ethylene oxide gas sterilizer
Classification	Class II (21 CFR 880.6860)
Medical Specialty	General Hospital
Product Code	FLF

Anprolene is a registered trademark of Andersen Sterilizers, Inc. The refill kits for the Anprolene AN75 Ethylene Oxide Gas Sterilizer, including the accessories (sterilization bags, AN7514 cartridges, and AN87 Dosimeter®), are registered with the US Environmental Protection Agency (EPA#69340-9).

Primary Predicate Device - EOGas 4 Sterilizer

Device Name	EOGas 4® Ethylene Oxide Gas Sterilizer
510(k) number	K150646
Manufacturer	Andersen Sterilizers, Inc.

For the subject device, the sterilization temperature, sterilization time, and post-sterilization ventilation time were modified from the predicate device. The Anprolene AN75 Ethylene Oxide Sterilizer operates at 20-29°C with an exposure time of 12 hours and ventilation of 2 hours, whereas the primary predicate device operates at 50±3°C with an exposure time of 3 hours and 30 minute ventilation. The principles of operation, intended use, and technology are otherwise substantially equivalent.

Pre-amendment Device - B-2270/AN70 Anprolene Sterilizer

Device Name B-2270/AN70 Anprolene Sterilizer
Ethylene Oxide Sterilization System
510(k) number NA
Manufacturer Andersen Products, Inc.

The Andersen B-2270/AN70 Anprolene Sterilizer is a pre-amendment predicate device. It was in commercial distribution and clinical use in the United States prior to May 28, 1976.

For the subject device, the material composition of the sterilization bag, the ethylene oxide delivery method, and the sterilization cabinet design of the pre-amendment device were modified. No modifications were made to the technology or intended use.

Device Description

The Anprolene AN75 Ethylene Oxide Gas Sterilizers, model numbers AN75i (AN75.64 and AN75.65), AN75iX (AN75.84 and AN75.85), and AN75J (AN75.74 and AN75.75), are intended to sterilize moisture, temperature, chemical corrosion, or radiation-sensitive reusable medical devices in healthcare facilities. The sterilant is a unit dose of 100% ethylene oxide contained in a cartridge, and the sterilization chamber is a gas-impervious flexible sterilization bag. Each sterilization cycle is monitored using cumulative gas exposure measurement (AN87 Dosimeter), as well as a *Bacillus atrophaeus* biological indicator (AN2203) inserted into a process challenge device (AN7508.14 Anprolene SteriTest) that is integrated into the sterilizer.

Indications for Use

The Anprolene AN75 Ethylene Oxide Gas Sterilizer is intended for use in hospitals and other human healthcare settings. It is designed to sterilize reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation.

The 12 hour cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer is for surface sterilization of medical devices, including mated surfaces. The 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 (68-84°F)	35-70%	12 hours	14 hours

Maximum loads of specific materials and devices that have been validated are listed in **Table 2**. All validated maximum loads were processed without additional devices in the sterilizer.

Table 2. Load and material types validated in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

Device Type	Maximum Load	Device Examples	Required Aeration
Metal	24 lbs (11 kg)	Delicate sharps and surgical instruments, including those with hinges and mated surfaces	Metal instruments do not absorb EO; Follow pouch or wrap manufacturer's instructions (Examples: Sterisheet® wrap require ≥ 6 hours at 20-29°C).
Plastic	3.5 lbs (1.6 kg)	Reusable power cords, trocars	Follow manufacturer's instructions; 24 hours at 20-29°C.
Fabric	3.0 lbs (1.4 kg)	Reusable cloth gowns, towels	Follow manufacturer's instructions; 24 hours at 20-29°C.

Reusable medical devices must be aerated following the instructions of device manufacturers and packaging material manufacturers, then released for use after sterilization based on successful inactivation of an EZTest®- Gas Biological Indicator in the Anprolene SteriTest process challenge device.

Substantial Equivalence Comparison

The Anprolene AN75 Ethylene Oxide Gas Sterilizer is substantially equivalent to the predicate devices: the B-2270/AN70 Anprolene Sterilizer and the EOGas 4 Ethylene Oxide Gas Sterilizer, because all three sterilizers are intended for the same use, designed in a similar way, use similar technology, and perform substantially equivalently.

The Anprolene AN75 Ethylene Oxide Gas Sterilizer differs from the predicate B-2270/AN70 Anprolene sterilizer in the use of a sterilization bag that is ethylene oxide impermeable, gas delivery from an ampoule in a cartridge rather than an ampoule in a gas release bag, and a ventilated sterilization cabinet surrounding the sterilization bag. Compared to the predicate EOGas 4 sterilizer, the Anprolene AN75 Ethylene Oxide Gas Sterilizer has a gas exposure of 12 hours at 20-29°C rather than 3 hours at 50±3°C. Ventilation after sterilization is 2 hours for the subject Anprolene AN75 sterilizer, and 30 minutes for the predicate EOGas 4 sterilizer. These differences raise no issues related to safety or effectiveness of the subject device sterilization cycle. A comparison among the sterilizers is listed in **Table 3**.

Table 3: Comparison among the Anprolene AN75 Ethylene Oxide Gas Sterilizer, the B-2270/AN70 Anprolene Ethylene Oxide Gas Sterilizer, and the EOGas 4 Ethylene Oxide Gas Sterilizer

	Predicate EOGas 4 Sterilizer (K150646)	**Predicate B-2270/AN70 Anprolene Sterilizer**	**Subject Anprolene AN75 Sterilizer**	**Comparison**
Intended Use	Indoor ethylene oxide sterilizer in a healthcare setting			Same
Indications for Use	Intended for use in hospitals and other human healthcare settings			Same
	Designed to sterilize reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation			Same
	3 hour EO exposure at 50±3°C with 0.5 hr mandatory ventilation	12 hour EO exposure at 20-29°C with 2 hrs mandatory ventilation		Equivalent
	For surface sterilization and sterilization of single-lumen flexible endoscopes	For surface sterilization, including mated surface		
Design	Ventilated cabinet	Stainless steel container	Ventilated cabinet	Equivalent
	Unit dose EO in cartridge	Unit dose EO in gas release bag	Unit dose EO in cartridge	
	Flexible sterilization chamber			
	EO impermeable sterilization bag	Gas-diffusion sterilization bag	EO impermeable sterilization bag	
Technology	Use EO as sterilant; EPA registered			Same
	Critical parameters: EO concentration, RH, temperature, and time			
Biological Monitoring	EOGas 4 SteriTest	AN80 Steritest	Anprolene SteriTest	Equivalent
Safety	Verified compliance for electromagnetic compatibility and electrical safety; Human Factors evaluation for safety and effectiveness.	N/A	Verified compliance for electromagnetic compatibility and electrical safety; Human Factors evaluation for safety and effectiveness.	Same
Performance	Sterilize reusable medical devices as defined in the sterilizer labeling to a SAL of 10^{-6} with reasonable assurance of safety and effectiveness	Sterilize reusable medical devices as defined in the sterilizer labeling	Sterilize reusable medical devices as defined in the sterilizer labeling to a SAL of 10^{-6} with reasonable assurance of safety and effectiveness	Equivalent

Performance Testing

The Anprolene AN75 Ethylene Oxide Gas Sterilizer has been validated using applicable tests in the FDA 1993 "Guidance on Premarket Notification [510(k)] Submissions for Sterilizers Intended for Use in Health Care Facilities".

The maximum loads of metal, fabric, and plastic devices that may be routinely sterilized in the Anprolene AN75 Ethylene Oxide Gas Sterilizer were defined and validated. Using the 12 hour cycle at 20-29°C, the Anprolene AN75 sterilization system reproducibly and effectively sterilizes 24 lbs of metal instruments with or without mated surfaces, 3.0 lbs of fabric, and 3.5 lbs of plastic devices, achieving a minimum sterility assurance level (SAL) of 10^{-6}. All validated maximum loads were processed without additional devices in the sterilizer. A compatible carrier for EO sterilization (a perforated metal basket) was used to hold the metal and plastic devices, for the convenience of handling relatively large quantities of devices.

The validation testing demonstrated that exposure to EO gas under the defined loads and physical parameters achieved a minimum sterility assurance level (SAL) of 10^{-6} for surfaces, including mated surfaces. The effectiveness of the sterilization process for the loads was confirmed by successful sterilization in simulated-use testing using instruments with mated surfaces.

Process residue analysis showed that after recommended aeration, EO residuals on the most absorbent materials tested in the study met the requirements of AAMI/ANSI/ISO 10993-7, demonstrating that the Anprolene AN75 Ethylene Oxide Gas Sterilizer and its accessories are safe to use if the guidance and instructions are followed. The Anprolene AN75 Ethylene Oxide Gas Sterilizer was tested to verify compliance with requirements for electromagnetic compatibility and electrical safety.

Physical performance tests demonstrated that the Anprolene AN75 Ethylene Oxide Gas Sterilizer, gas cartridges, and sterilization bags met their performance specifications. The Anprolene AN75 sterilization system achieved and maintained the cycle specifications for EO concentration, temperature, time, and relative humidity. Both the sterilizer and the accessories consistently operated in accordance with predetermined criteria. The 12 hour cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer was repeatable and reliable under the indicated test load conditions.

Shelf Life testing demonstrated that the AN7514 cartridges maintain performance specifications (physical characteristics, released EO amount, EO concentration, and inactivation of biological indicators) throughout the stated shelf life of 5 years, demonstrating reasonable assurance for effectiveness.

Conclusion

The Anprolene AN75 Ethylene Oxide Gas Sterilizer is substantially equivalent to the pre-amendment predicate Andersen B-2270/AN70 Anprolene Sterilizer, and the predicate EOGas 4® Ethylene Oxide Gas Sterilizer (K150646).