**DEPARTMENT OF HEALTH & HUMAN SERVICES** Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 18, 2015

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

Re: K150646
Trade/Device Name: EOgas 4 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 20, 2015
Received: October 22, 2015

Dear Dr. 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 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 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,

Erin I. Keith -S

Erin I. Keith, M.S.
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)*
K150646

Device Name
EOGas 4 Ethylene Oxide Gas Sterilizer, AN4000.01 and AN4000.11

Indications for Use *(Describe)*
The EOGas 4 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 3 hour cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer is for surface sterilization of medical devices as well as for the sterilization of single-lumen flexible endoscopes. The critical process parameters for the cycle are summarized 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 | 35-70% | 3 hours | 3.5 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 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 | |

Reusable medical devices must be aerated following the instructions of the device manufacturer and the packaging material manufacturer, then released for use after sterilization based on successful inactivation of an EZTest®- Gas Biological Indicator in the Andersen EOGas 4 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.

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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 17, 2015

5.4 Device

| | |
|---|---|
| Proprietary Name | EOGas 4® Ethylene Oxide Gas Sterilizer<br>Models AN4000.01 and AN4000.11 |
| Common Name | Ethylene oxide gas sterilizer |
| Classification | Class II (21 CFR 880.6860) |
| Medical Specialty | General Hospital |
| Product Code | FLF |

The refill kits for the EOGas 4 Ethylene Oxide Gas Sterilizer, including the accessories (sterilization bags, EOGas 4 cartridges, AN1087 Dosimeters®, and Humidichips®), are registered with the US Environmental Protection Agency (EPA #69340-7).

5.5 Predicate Device - Sterijet

| | |
|---|---|
| Device Name | Sterijet Ethylene Oxide Sterilization System |
| 510(k) number | NA |
| Manufacturer | Andersen Products, Inc. |

The Sterijet sterilization system is a pre-amendment predicate (marketed for hospital use in the United States prior to the Medical Device Act). It has been in continuous use for commercial ethylene oxide sterilization since the early 1970's, although it was taken off the hospital market due to changes in EPA regulation of ethylene oxide-chlorofluorocarbon mixtures.

The purpose for this submission is to modify the sterilization bag and the ethylene oxide delivery method compared to the pre-amendment device. No modifications were made to the technology or intended use.

## 5.6 Predicate Device - Steri-Vac 4XL

| | |
|---|---|
| Device Name | Steri-Vac™ 4XL Gas Sterilizer |
| 510(k) number | K812867 |
| Manufacturer | 3M™ Company |

The EOGas 4 Ethylene Oxide Sterilizer uses a flexible sterilization bag as a sterilization chamber, whereas the predicate device has a fixed sterilization chamber. The principles of operation, intended use, and technology are otherwise substantially equivalent.

## 5.7 Device Description

The EOGas 4 Ethylene Oxide Gas Sterilizer, model AN4000.01 (115V) or AN4000.11 (230V), is 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 (AN1087 Dosimeter), as well as a *Bacillus atrophaeus* biological indicator (AN2203) inserted into a process challenge device (AN7408.14 Andersen EOGas 4 Steritest) that is integrated into the sterilizer.

## 5.8 Indications for Use

The EOGas 4 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 3 hour cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer is for surface sterilization of medical devices as well as for the sterilization of single-lumen flexible endoscopes. The 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

| EO Amount | Temperature | Relative Humidity | EO Exposure Time | Total Cycle Time |
|---|---|---|---|---|
| 17.6 g ± 5% | 50°C ± 3°C | 35-70% | 3 hours | 3.5 hours |

Maximum loads of specific materials and devices that have been validated are listed in **Table 5-2**. All validated maximum loads were processed without additional devices in the sterilizer.

**Table 5-2.** 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 | |

Reusable medical devices must be aerated following the instructions of the device manufacturer and the packaging material manufacturer, then released for use after sterilization based on successful inactivation of an EZTest® - Gas Biological Indicator in the Andersen EOGas 4 SteriTest process challenge device.

## 5.9 Substantial Equivalence Comparison

The EOGas 4 Ethylene Oxide Gas Sterilizer is substantially equivalent to the predicate devices: the Sterijet Ethylene Oxide Sterilization System and the Steri-Vac 4XL Gas Sterilizer, because all three sterilizers are intended for the same use, designed in a similar way, use the same technology, and perform substantially equivalently.

The EOGas 4 Ethylene Oxide Gas Sterilizer differs from the predicate Sterijet sterilizer in the use of a sterilization bag that is ethylene oxide impermeable and gas delivery from a cartridge rather than direct injection. The EOGas 4 Ethylene Oxide Gas Sterilizer differs from the predicate Steri-Vac 4XL sterilizer in the use of a flexible sterilization bag rather than a fixed sterilization chamber, and the use of approximately 20% of the ethylene oxide per cycle that is used in the predicate. 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 5-3**.

**Table 5-3.** Comparison among the EOGas 4 Ethylene Oxide Gas Sterilizer, the Sterijet Ethylene Oxide Sterilization System, and the Steri-Vac 4XL Gas Sterilizer

| | Sterijet System | 4XL Sterilizer | EOGas 4 Sterilizer | Comparison |
|---|---|---|---|---|
| **Intended Use** | Indoor ethylene oxide sterilizer in a healthcare setting | | | Same |
| **Indications for Use** | Sterile processing of reusable medical devices using ethylene oxide | Sterilization of heat and/or moisture sensitive devices using ethylene oxide | Sterilization of reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation | Equivalent |
| **Design** | Gas injection cabinet and aerator | Similar design for exterior and cabinet | | Equivalent. Similar designs with flexible chamber and unit dose EO in the EOGas 4 sterilizer |
| | Injection of EO from a tank; amount depending on bag size | Unit dose EO | Unit dose EO | |
| | Flexible sterilization chamber | Fixed sterilization chamber | Flexible sterilization chamber | |
| | Gas-diffusion bag | EO impervious chamber | EO impervious bag | |
| **Technology** | Use EO as sterilant; EPA registered | | | Same |
| | Critical parameters: EO concentration, RH, temperature, and time | | | |
| **Biological Monitoring** | N/A | 3M™ Attest™ EO Pack placed in the load; resistance equivalent to an AAMI routine syringe test pack | AN7408.14 process challenge device integrated into the sterilizer; resistance greater than the validated worst-case loads in the sterilizer | Equivalent: confirm appropriate sterilization parameters have been met. |
| **Safety** | Verify compliance for electromagnetic compatibility and electrical safety | | | Same |
| **Performance** | Sterilize reusable medical devices as labeled to a SAL of $10^{-6}$ with reasonable assurance of safety and effectiveness | | | Equivalent |

## 5.10 Performance Testing

The EOGas 4 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, plastic, and single-lumen flexible endoscopes that may be routinely sterilized in the EOGas 4 Ethylene Oxide Gas Sterilizer were defined and validated. Using the 3 hour cycle at 50°C, the EOGas 4 sterilization system reproducibly and effectively sterilizes 24 lbs of metal instruments with or without mated surfaces, 6.1 lbs of fabric, 7.0 lbs of

plastic devices, and four 1.2 x 700 mm endoscopes or one 2 x 1100 mm endoscope, achieving a minimum sterility assurance level of $10^{-6}$. All validated maximum loads were processed without additional devices in the sterilizer.

The Andersen process challenge device, consisting of a BI receptacle with a self-contained biological indicator, was developed for the 3 hr cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer. It represents a rigorous challenge to the EOGas 4 sterilization process as it impedes gas diffusion, heating, and humidification. Its resistance characteristics are greater than the same BI placed in the worst-case location in each of the worst-case validation loads.

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, mated surfaces, and endoscope lumens. The effectiveness of the sterilization process for the loads was confirmed by successful sterilization in simulated-use testing using instruments with mated surfaces as well as endoscope lumens. In addition, in-use testing confirmed the ability of the cycle to sterilize single-lumen endoscopes used clinically in a hospital setting.

Process residue analysis showed that the majority of EO or ethylene chlorohydrin residuals remaining on even the most absorbent materials tested in the study met the requirements of AAMI/ANSI/ISO 10993-7, demonstrating that the EOGas 4 Ethylene Oxide Gas Sterilizer and its accessories are safe to use if the guidance and instructions are followed. The EOGas 4 Ethylene Oxide Gas Sterilizer was tested to verify compliance with requirements for electromagnetic compatibility and electrical safety.

Physical performance tests demonstrated that the EOGas 4 Ethylene Oxide Gas Sterilizer, EOGas cartridges, sterilization bags, and Humidichips met their performance specifications. The EOGas 4 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 3 hour cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer was repeatable and reliable under the indicated test load conditions.

Conclusion:
The EOGas 4 Ethylene Oxide Gas Sterilizer is substantially equivalent to the predicate devices.