November 12, 2020

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

Re: K192978
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 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)*
K192978

Device Name
EOGas 4 Ethylene Oxide Gas Sterilizer

Indications for Use *(Describe)*

The EOGas 4 Ethylene Oxide Gas Sterilizer is designed to sterilize reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation. The critical process parameters for the two available cycles are summarized below:

Table 1. EOGas 4 Ethylene Oxide Sterilizer cycle parameters

EO Exposure Time	Total Cycle Time	EO Amount	Temperature	Relative Humidity
3 hours	3.5 hours	17.6 g ± 5%	50°C ± 3°C	35-70%
6 hours	7 hours			

The differences between the two options are the length of EO gas exposure and the length of mandatory ventilation after gas exposure; the gas exposure is chosen based on the devices to be sterilized. The appropriate purge probe and process challenge device (PCD) must be used: EOGas 4 SteriTest for a 3-hour gas exposure, EOGas 4 Endo-SteriTest for a 6-hour gas exposure.

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 with working length shorter than 1100 mm as specified in the labeling. The EOGas 4 SteriTest PCD is used with the 3-hour gas exposure.

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 labeling. The EOGas 4 Endo-SteriTest PCD is used with the 6-hour gas exposure.

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

Reusable medical devices must be aerated following the instructions of the device manufacturer and the packaging material manufacturer. Devices are released for use after sterilization based on successful inactivation of a biological indicator (BI) in the Andersen EOGas 4 SteriTest (3-hour gas exposure) or EOGas 4 Endo-SteriTest (6-hour gas exposure) process challenge devices.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
K192978

Applicant's Name and Address

Andersen Sterilizers, Inc.
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	EOGas 4 Ethylene Oxide Gas Sterilizer
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, Dosimeters, and Humidichips), are registered with the US Environmental Protection Agency (EPA #69340-7).

Predicate Device

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

The principles of operation for the EOGas 4 Ethylene Oxide Sterilizer, intended use, and technology are unchanged. The predicate EOGas 4 Ethylene Oxide Gas Sterilizer has the option of a 3-hour gas exposure or a 5-hour gas exposure, although only the 3-hour gas exposure is indicated for sterilization in hospitals and other human healthcare settings. To add the sterilization of duodenoscopes and colonoscopes to the indications for use, the 5-hour gas exposure was lengthened to 6 hours and a new process challenge device was developed appropriate for the longer cycle.

Device Description

The EOGas 4 Ethylene Oxide Gas Sterilizer, model AN4000.60 (115V) or AN4000.61 (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.

Indications for Use

The EOGas 4 Ethylene Oxide Gas Sterilizer is designed to sterilize reusable medical devices that are sensitive to moisture, heat, chemical corrosion, or radiation. The critical process parameters for the two available cycles are summarized below:

Table 1. EOGas 4 Ethylene Oxide Sterilizer cycle parameters

EO Exposure Time	Total Cycle Time	EO Amount	Temperature	Relative Humidity
3 hours	3.5 hours	17.6 g ± 5%	50°C ± 3°C	35-70%
6 hours	7 hours			

The differences between the two options are the length of EO gas exposure and the length of mandatory ventilation after gas exposure; the gas exposure is chosen based on the devices to be sterilized. The appropriate purge probe and process challenge device (PCD) must be used: EOGas 4 SteriTest for a 3-hour gas exposure, EOGas 4 Endo-SteriTest for a 6-hour gas exposure.

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 with working length shorter than 1100 mm as specified in the labeling. The EOGas 4 SteriTest PCD is used with the 3-hour gas exposure.

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 labeling. The EOGas 4 Endo-SteriTest PCD is used with the 6-hour gas exposure.

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 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		

Reusable medical devices must be aerated following the instructions of the device manufacturer and the packaging material manufacturer. Devices are released for use after sterilization based

on successful inactivation of a biological indicator (BI) in the Andersen EOGas 4 SteriTest (3-hour gas exposure) or EOGas 4 Endo-SteriTest (6-hour gas exposure) process challenge devices.

Technological Characteristics Comparison Table

The EOGas 4 Ethylene Oxide Gas Sterilizer is compared to the predicate device – the EOGas 4 Ethylene Oxide Gas Sterilizer (**K150646**), because the sterilizers are intended for the same use, designed in the way and use the same technology. The predicate EOGas 4 Ethylene Oxide Gas Sterilizer has the option of a 3-hour gas exposure or a 5-hour gas exposure. To sterilize a load consisting of two duodenoscopes or colonoscopes at a time, the 5-hour gas exposure was lengthened to 6 hours, and a process challenge device was created, the EOGas 4 Endo-SteriTest, that is appropriate for the longer gas exposure. A comparison between the sterilizers is listed in **Table 3**.

Table 3. Comparison between the EOGas 4 Ethylene Oxide Gas Sterilizer and the predicate EOGas 4 Ethylene Oxide Gas Sterilizer

	Subject EOGas 4 Sterilizer K192978	**Predicate EOGas 4 Sterilizer K150646**	**Comparison**
Intended Use	Indoor EO sterilizer in a healthcare setting with a SAL of 10^{-6}		Same
Design	Same design for exterior and cabinet		Same
	Same unit dose EO; Same EO impervious sterilization bag		
	Same flexible sterilization chamber		
Technology	Use EO as sterilant; EPA registered		Same
	Critical parameters: EO concentration, RH, temperature, and time		
Safety	Verify compliance for electromagnetic compatibility and electrical safety		Same
Indications for Use	3-hour gas exposure at 50°C; 6-hour gas exposure at 50°C	3-hour gas exposure at 50°C; (5-hour gas exposure at 50°C; not used for healthcare sterilization)	Added a 6-hour gas exposure for sterilization of endoscopes with > 1100 mm working length
Process Challenge Device	EOGas 4 Endo-SteriTest **(K192980)** EZTest-Gas BI (**K930683**); Bionova BT110 RRBI (**K191021**); BI Receptacle: Stainless steel cylinder 0.020” ID x 4.50” L lumen	EOGas 4 SteriTest (**K151585**) EZTest-Gas BI (**K930683**); BI Receptacle: Stainless steel cylinder 0.020” ID x 0.25” L orifice	Similar: appropriate for the intended length of gas exposure
Performance	Sterilize reusable medical devices as labeled to a SAL of 10^{-6}		Similar

Summary of Non-Clinical Testing:

Table 4. Summary of Non-Clinical Testing

Time	Purpose	Acceptance Criteria	Results
Minimum Sterilization Parameters	To define and validate the endoscope loads that can be sterilized using the 6-hour gas exposure at 50°C in an EOGas 4 sterilizer	The EO gas exposure time at 50°C in an EOGas 4 sterilizer must result in sterilization of the endoscope loads.	Using a 6-hour EO gas exposure in the EOGas 4 sterilizer, 6-Log biological indicators were consistently inactivated for two duodenoscopes, two colonoscopes, or one colonoscope and one duodenoscope in each load. The minimum parameters for sterilization of two duodenoscopes or colonoscopes are 518 mg/L EO, 46.4°C, and 35% RH.
Half Dose Validation	To demonstrate the repeatability of the EOGas 4 sterilization process, and that a SAL of 10^{-6} is achieved for duodenoscope and colonoscope sterilization	For consecutive half dose cycles and full dose cycles: EO concentration is half when half the amount of EO is used. All 6-Log *Bacillus atrophaeus* biological indicators, inoculated at the worst-case locations of the tested endoscopes, are inactivated.	Consecutive half dose cycles and full dose cycles were performed. The EO concentration was half when half the amount of EO was used. The cumulative lethality of half dose cycles was half the lethality of full dose cycle. The cycles consistently inactivated all 6-Log *Bacillus atrophaeus* biological indicators inoculated at the midpoint of the tested channels and at the elevator mechanism of duodenoscopes, as well as the water jet channel of the colonoscopes.
Simulated-Use Testing	To demonstrate the successful sterilization of duodenoscopes and colonoscopes within the claims under a worst-case scenario	For consecutive full dose cycles: Biological indicators with 6-Log *Bacillus atrophaeus*, prepared in an artificial soil and inoculated at the worst-case locations of the tested endoscopes, are inactivated.	Biological indicators with 6-Log *Bacillus atrophaeus* were prepared in an artificial soil and inoculated at the center of the tested channels and at the elevator mechanism of duodenoscopes as well as the water jet channel of the colonoscopes. Inactivated biological indicators were obtained in all cycles for all duodenoscope and colonoscope loads tested.
Test	**Purpose**	**Acceptance Criteria**	**Results**

In-Use Testing	To demonstrate that the 6-hour cycle at 50°C in an EOGas 4 sterilizer successfully sterilizes duodenoscopes and colonoscopes used in routine endoscopic procedures in a hospital or clinic setting	Duodenoscopes and colonoscopes, used on the patients, cleaned but not disinfected, are sterilized using the 6-hour cycle at 50°C in an EOGas 4 sterilizer.	Duodenoscopes and colonoscopes, used on patients, were cleaned per hospital protocol but not disinfected, processed using the 6-hour EO exposure at 50°C in the EOGas 4 sterilizer; sterility was tested by a flush method per USP. All test cultures from the processed duodenoscopes and colonoscopes were sterile.
EO Residuals	To demonstrate that endoscopes and their accessories are safe to use if the guidance and instructions are followed	After additional aeration following the cycle, EO residuals on duodenoscopes and colonoscopes are evaluated, and the residuals on the endoscopes and accessories meet the requirements of ANSI/AAMI/ISO 10993-7.	Olympus TJF-Q180V, TJF-Q160VF, TJF-Q190V, PJF-160, CF-Q180AL, Pentax ED34-i10T2, ED-3490TK duodenoscopes and EC-3490Li colonoscopes wrapped in Sterisheet must aerate for an additional 6 hours after the cycle. Fujifilm ED-530XT and EC-600HL wrapped in Sterisheet must aerate for an addition 8 hours after the cycle. After 6 hours of additional aeration, EO residuals on the packaging materials met the requirements of ANSI/AAMI/ISO 10993-7.

The EOGas 4 Ethylene Oxide Gas Sterilizer 6-hour gas exposure 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".

Duodenoscopes used in these studies include:

- Olympus TJF-Q180V
- Olympus TJF-Q160VF
- Olympus TJF-Q190V
- Olympus PJF-160
- Fujifilm ED-530XT
- Pentax ED34-i10T2
- Pentax ED-3490TK

Colonoscopes used include:

- Olympus CF-Q180AL
- Fujifilm EC-600HL
- Pentax EC-3490Li

The maximum loads of duodenoscopes or colonoscopes that may be routinely sterilized in the

EOGas 4 Ethylene Oxide Gas Sterilizer were defined and validated. Using a 6-hour gas exposure at 50°C, the EOGas 4 sterilization system reproducibly and effectively sterilizes two duodenoscopes, two colonoscopes, or one duodenoscope paired with one colonoscope, achieving a minimum sterility assurance level of 10^{-6}.

The EOGas 4 Endo-SteriTest process challenge device, consisting of a BI receptacle with a self-contained biological indicator, was developed for the 6-hour gas exposure 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 locations in the two duodenoscope or two colonoscope loads.

The validation testing demonstrated that exposure to EO gas under the defined load and physical parameters achieved a minimum sterility assurance level of 10^{-6} for two duodenoscopes, two colonoscopes, or one duodenoscope paired with one colonoscope, in each load. The effectiveness of the sterilization process for the loads was confirmed by successful sterilization in simulated-use testing. In addition, in-use testing confirmed the ability of the cycle to sterilize duodenoscopes or colonoscopes used clinically in a hospital setting.

Process residue analysis showed that the EO residuals remaining on the duodenoscopes or colonoscopes tested in the study, after an additional aeration of 6 hours (for Olympus duodenoscopes, Olympus colonoscopes, and Pentax duodenoscopes) or 8 hours (for Fujifilm duodenoscopes and colonoscopes), met the requirements of ANSI AAMI 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.

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 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer was repeatable and reliable under the indicated test load conditions.

Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the EOGas 4 Ethylene Oxide Sterilizer is as safe, as effective, and performs as well as or better than the legally marketed predicate EOGas 4 Ethylene Oxide Sterilizer (**K150646**).