DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 18, 2015

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

Re: K151585
Trade/Device Name: Andersen EOgas 4 Steritest
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
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)*
K151585

Device Name
Andersen EOGas 4 SteriTest

Indications for Use *(Describe)*

The Andersen EOGas 4 SteriTest consists of a self-contained biological indicator inoculated with viable Bacillus atrophaeus bacterial spores that is placed in a dedicated BI receptacle in the sterilizer. It monitors the efficacy of 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

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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"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

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	Andersen EOGas 4® SteriTest
		Common Name	Biological Sterilization Process Indicator
		Classification	Class II (21 CFR 880.2800)
		Product Code	FRC
5.5	Predicate Device		
		Device Name	EZTest - Gas Biological Indicators
		510(k) number	K930683
		Manufacturer	Mesa Laboratories Inc.

This 510(k) submission modifies the indications for use of the predicate device in order to include it as a component in a process challenge device. No modifications were made to the technology or intended use.

5.6 Device Description

The Andersen EOGas 4® SteriTest consists of a single-use self-contained biological indicator (SCBI) placed in a reusable BI receptacle. It is designed for monitoring the efficacy of the 3 hour sterilization cycle at 50°C in an EOGas 4 Ethylene Oxide Gas Sterilizer.

The SCBI, the EZTest - Gas Biological Indicator, consists of a plastic vial that serves as the culture tube and a cap including a filter material port to allow ethylene oxide to enter the vial. The plastic vial contains *Bacillus atrophaeus* spores inoculated onto a paper carrier, and a glass ampoule containing modified soybean casein digest broth and phenol red acting as a pH indicator. There is a chemical indicator printed on the unit label of the SCBI to indicate EO exposure.

Following manufacturer's instructions, the operator inserts the Andersen EOGas 4 SteriTest into the reusable BI receptacle on the purge probe of the EOGas 4 Ethylene Oxide Gas Sterilizer, and initiates a 3 hour cycle at 50°C. After cycle completion, the SCBI is retrieved and activated by crushing the glass ampoule. The chemical indicator on the SCBI changes from blue to a green/brown color depending on the duration of ethylene oxide exposure. The activated SCBI and an unprocessed control are incubated at 30-35°C for 48 hours, and monitored for any color change and/or turbidity. Evidence of microbial growth by color change from red-orange to

yellow and/or turbidity must be interpreted as a failure to meet the conditions necessary for sterilization (cycle failed); no color change or turbidity indicates conditions for sterilization were achieved (cycle passed).

5.7 Indications for Use

The Andersen EOGas 4 SteriTest consists of a self-contained biological indicator inoculated with viable *Bacillus atrophaeus* bacterial spores that is placed in a dedicated BI receptacle in the sterilizer. It monitors the efficacy of 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

5.8 Device Comparison

The technological characteristics of the Andersen EOGas 4 SteriTest are substantially equivalent to the predicate device - EZTest - Gas Biological Indicators, because both indicators are intended for the same use, use the same technology, are designed in the same way, and perform substantially equivalently.

The Andersen EOGas 4 SteriTest differs from the predicate device in the configuration used in a load. 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 5-2**.

Table 5-2. Device Comparison

Element	EZTest - Gas BI	EOGas 4 SteriTest
Intended Use	Sterilization method: EO gas Process parameters: EO concentration, time, temperature, and relative humidity	Identical
Organism	*Bacillus atrophaeus* (ATCC 9372)	Identical
Viable Spore Population	$\geq 1.0 \times 10^6$	Identical
Device Design	Paper strip containing indicator organism; Glass ampoule containing growth medium; Capped vial serving as a culture tube; A pH indicator in medium for color change; A process indicator indicating EO exposure	Identical for the BI; Additionally, a BI receptacle is added to create a greater challenge to the sterilization process.
Materials of Construction	Paper, glass, and polypropylene	Paper, glass, polypropylene, and aluminum
Configuration in Load	SCBI placed within the load	SCBI in a receptacle

Indications for Use	Not available	The Andersen EOGas 4 SteriTest consists of a self-contained biological indicator inoculated with viable *Bacillus atrophaeus* bacterial spores that is placed in a dedicated BI receptacle in the sterilizer. It monitors the efficacy of the 3 hour sterilization cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.

5.9 Performance Testing

The Andersen EOGas 4 SteriTest has been validated using applicable tests in FDA 2007 "Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions", and AAMI/ANSI/ISO 11138-1 "Sterilization of health care products – Biological indicators - Part 1: General requirements" (FDA Recognition Number 14-296).

For the EZTest - Gas Biological Indicators, tests include viable spore population assay, resistance characteristics study, carrier and primary packaging materials (growth inhibition) evaluation, holding time assessment, and reduced incubation time validation. The results of all studies met the established acceptance criteria when applicable.

We also demonstrated that under the same exposure conditions, the resistance characteristics of the EZTest - Gas Biological Indicators were the same when measured in a Biological Indicator Evaluator Resistometer in the presence or absence of vacuum.

The Andersen EOGas 4 SteriTest represents a rigorous challenge to the EOGas 4 sterilization process. Its resistance characteristics are greater than the same EZTest-Gas Biological Indicator placed in the worst-case locations of the maximum fabric, metal, plastic, and endoscope validation loads. The performance of the Andersen EOGas 4 SteriTest in the 3 hour cycle at 50°C in an EOGas 4 Ethylene Oxide Gas Sterilizer is summarized in **Table 5-3**.

Table 5-3. Summary of bench tests performed to demonstrate safety and effectiveness of the Andersen EOGas 4 SteriTest

Test	Description	Result
Functionality	1) Critical parameters include temperature, time, and gas concentration under a relative humidity of 35-90%; 2) Device is appropriate for monitoring the efficacy of the sterilization process claimed	Pass
Shelf Life	Maintains performance specifications (resistance characteristics and correctly indicate pass/fail in cycles) throughout the stated shelf life of 2 years; Stability demonstrates reasonable assurance for effectiveness	Pass

In conclusion, the Andersen EOGas 4 SteriTest is substantially equivalent to the legally marketed predicate, the EZTest - Gas Biological Indicator.