March 3, 2021

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

Re: K202879
Trade/Device Name: EOGas 4 Endo-SteriTest RRBI
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: February 3, 2021
Received: February 4, 2021

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,

Clarence W. Murray, III, Ph.D.
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K202879

Device Name
EOGas 4 Endo-SteriTest RRBI

Indications for Use *(Describe)*

The EOGas 4 Endo-SteriTest Rapid Readout Biological Indicator consists of a self-contained biological indicator inoculated with viable Bacillus atrophaeus bacterial spores that is placed in a dedicated biological indicator receptacle mounted on the purge probe in the sterilizer. It monitors the efficacy of the 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.

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

Table 1. Critical parameters for the 6-hour gas exposure in the EOGas 4 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
17.6 g ± 5%	50°C ± 3°C	35-90%	6 hours	7 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K202879 510(k) Summary

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

March 3, 2021

Device

Proprietary Name	EOGas 4 Endo-SteriTest RRBI
Common Name	Biological Sterilization Process Indicator
Classification	Class II (21 CFR 880.2800)
Product Code	FRC

Predicate Device

Device Name	EOGas 4 SteriTest
510(k) number	**K151585**
Manufacturer	Andersen Sterilizers, Inc.

The current 510(k) submission modifies the predicate device to add a process challenge device for a 6-hour gas exposure. No modifications were made to the technology or intended use.

Device Description

The EOGas 4 Endo-SteriTest Rapid Readout Biological Indicator (RRBI) consists of a single-use self-contained biological indicator (SCBI) placed in a reusable biological indicator (BI) receptacle. It is designed for monitoring the efficacy of the 6-hour gas exposure at 50°C in an EOGas 4 Ethylene Oxide Gas Sterilizer.

The Bionova BT110 Rapid Readout Biological Indicator (**K191021**) 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 culture medium and a pH indicator. There is a chemical

indicator printed on the unit label of the SCBI to indicate EO exposure by changing color from brown/red to green.

Following manufacturer's instructions, the operator inserts the Bionova BT110 Rapid Readout Biological Indicator into the reusable BI receptacle on the dedicated purge probe of the EOGas 4 Ethylene Oxide Gas Sterilizer, and initiates a 6-hour gas exposure 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 brown/red to a green color after ethylene oxide exposure.
The activated SCBI and an unprocessed control are incubated in a Terragene Bionova IC10/20FR, IC10/20FRLCD or MiniBio Auto-Reader Incubator for 4 hours to detect fluorescent activity or 48 hours to detect color change. Evidence of microbial growth by presence of fluorescent activity or color change from blue to yellow must be interpreted as a failure to meet the conditions necessary for sterilization (cycle failed); no fluorescence or no color change indicates conditions for sterilization were achieved (cycle passed).

Indications for Use

The EOGas 4 Endo-SteriTest Rapid Readout Biological Indicator consists of a self-contained biological indicator inoculated with viable *Bacillus atrophaeus* bacterial spores that is placed in a dedicated biological indicator receptacle mounted on the purge probe in the sterilizer. It monitors the efficacy of the 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.

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

Table 1. Critical parameters for the 6-hour gas exposure 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%	6 hours	7 hours

Technological Characteristics

Table 2 below compares the technological characteristics of the EOGas 4 Endo-SteriTest RRBI to the technological characteristics of the predicate device, EOGas 4 SteriTest (**K151585**).

Table 2. Device Comparison

Element	**EOGas 4 SteriTest (K151585)**	**EOGas 4 Endo-SteriTest RRBI (K202879)**	**Comparison**
Intended Use	Sterilization method: EO gas Process parameters: EO concentration, time, temperature, and relative humidity	Sterilization method: EO gas Process parameters: EO concentration, time, temperature, and relative humidity	Same
Organism	*Bacillus atrophaeus* (ATCC 9372)	*Bacillus atrophaeus* (ATCC 9372)	Same
Viable Spore Population	$\geq 1.0 \times 10^6$	$\geq 1.0 \times 10^6$	Same
Device Design	EZTest-Gas BI **(K930683)** Paper strip containing indicator organism; Glass ampoule containing growth medium; Capped vial serving as a culture tube; pH indicator in medium for color change; Process indicator indicating EO exposure.	Bionova BT110 RRBI (**K191021)** Paper strip containing indicator organism; Glass ampoule containing growth medium; Capped vial serving as a culture tube; pH indicator in medium for color change; Process indicator indicating EO exposure; Fluorescent enzymatic activity detection.	Similar
	BI receptacle: Creates a greater challenge to the sterilization process than the worst-case location of the worst-case load in the IFU statement; For the 3-hour gas exposure	BI receptacle: Creates a greater challenge to the sterilization process than the worst-case location of the worst-case load in the IFU statement; For the 6-hour gas exposure	Different
	Purge probe: Blue color	Purge probe: Gold color	Different
Materials of Construction	Paper, glass, polypropylene, and aluminum	Paper, glass, polypropylene, and stainless steel	Different
Configuration in Load	SCBI in a receptacle	SCBI in a receptacle	Same
Indications for Use	The 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 gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.	The EOGas 4 Endo-SteriTest RRBI consists of a self-contained biological indicator inoculated with viable *Bacillus atrophaeus* bacterial spores that is placed in a dedicated biological indicator receptacle mounted on the purge probe in the sterilizer. It monitors the efficacy of the 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.	Different

Performance Testing

The EOGas 4 Endo-SteriTest RRBI has been validated using applicable tests in FDA 2007 "Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions", and ANSI/AAMI/ISO 11138-1:2017 "Sterilization of health care products - Biological indicators - Part 1: General requirements" (FDA Recognition Number 14-502).

For the Bionova BT110 Rapid Readout Biological Indicators **(K191021),** tests included viable spore population assay, resistance characteristics study, carrier and primary packaging materials (growth inhibition) evaluation, holding time assessment, reduced incubation time validation, recovery protocols for recovery medium, visual readout stability, and in-field evaluation. The results of all studies met the established acceptance criteria.

The EOGas 4 Endo-SteriTest RRBI represents a rigorous challenge to the EOGas 4 sterilization process. Its resistance characteristics are greater than the same biological indicator placed in the worst-case location of the endoscope validation loads. The performance of the EOGas 4 Endo-SteriTest RRBI in the 6-hour gas exposure at 50˚C in an EOGas 4 Ethylene Oxide Gas Sterilizer is summarized in **Table 3**.

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

Test	Description	Result
Functionality	1) Critical parameters include time, temperature, gas concentration, and relative humidity 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

Conclusion:
In conclusion, the EOGas 4 Endo-SteriTest RRBI is substantially equivalent to the legally marketed predicate, the EOGas 4 SteriTest (**K151585**).