November 12, 2020

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

Re: K192980
Trade/Device Name: EOGas 4 Endo-SteriTest
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: FRC
Dated: October 28, 2020
Received: October 29, 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

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)*

K192980

Device Name
EOGas 4 Endo-SteriTest

Indications for Use *(Describe)*

The EOGas 4 Endo-SteriTest 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 a gold-colored 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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# 510(k) Summary
# K192980

## 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 28, 2020

## Device

| | |
|---|---|
| Proprietary Name | EOGas 4 Endo-SteriTest |
| 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. |

This 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 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 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 EZTest-Gas 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 EZTest-Gas Biological Indicator 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).

## Indications for Use

The EOGas 4 Endo-SteriTest 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 a gold-colored 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 Comparison

The technological characteristics of the EOGas 4 Endo-SteriTest are compared to the predicate device, EOGas 4 SteriTest (**K151585**), because both process challenge devices (PCDs) are intended for the same use, use the same technology, are designed in the same way, and perform similarly.

The EOGas 4 Endo-SteriTest differs from the predicate device in the resistance to the sterilization process. A comparison between the devices is listed in **Table 2**.

**Table 2.** Device Comparison

| Element | EOGas 4 SteriTest (K151585) | EOGas 4 Endo-SteriTest (K192980) |
|---|---|---|
| Intended Use | Sterilization method: EO gas<br>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 | SCBI<br>Paper strip containing indicator organism;<br>Glass ampoule containing growth medium;<br>Capped vial serving as a culture tube;<br>A pH indicator in medium for color change;<br>A process indicator indicating EO exposure. | SCBI<br>Identical |
| | BI receptacle<br>Creates a greater challenge to the sterilization process than the worst-case location of the worst-case load in the IFU statement;<br>For the 3-hour gas exposure | BI receptacle<br>Same;<br>Modified for a 6-hour gas exposure used for duodenoscope and colonoscope sterilization |
| | Purge probe<br>Blue color | Purge probe<br>Gold color |
| Materials of Construction | Paper, glass, polypropylene, and aluminum | Paper, glass, polypropylene, and stainless steel |
| Configuration in Load | SCBI in a receptacle | Identical |
| 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 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 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer. |

## Summary of Non-Clinical Testing:

The EOGas 4 Endo-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 ANSI AAMI ISO 11138-1 "Sterilization of health care products – Biological indicators - Part 1: General requirements" (FDA Recognition Number 14-502).

For the EZTest-Gas Biological Indicators, tests included 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.

Under equivalent exposure conditions, the resistance characteristics of the EZTest-Gas Biological Indicators were identical when measured in a Biological Indicator Evaluator Resistometer in the presence or absence of a vacuum.

The EOGas 4 Endo-SteriTest 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 locations of the endoscope validation loads. The performance of the EOGas 4 Endo-SteriTest 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

| Test | Description | Acceptance Criteria | Result |
|---|---|---|---|
| **EZTest-Gas Biological Indicator Performance Characteristics** | | | |
| Viable Spore Population Assays | Determine spore population and demonstrate stability within 50% to 300% of the certified value during the claimed shelf life | $\geq 10^6$ microorganisms per unit;<br><br>Stable for the stated 2-year shelf life | Meets the specifications for spore population according to 2007 FDA BI guidance and ANSI/AAMI/ISO 11138-1 |
| Resistance Characteristics Study | Determine D-value using the fraction negative method | D-value ≥ 3 min;<br>Survival/Kill Time: 15 min;<br>D-values remain ±20% of the stated value for the claimed 2-year shelf life | Meets the specifications for resistance characteristics according to 2007 FDA BI guidance and ANSI/AAMI/ISO 11138-1 |
| Growth Inhibition | Evaluate the effect of the carrier and the primary packaging materials for the intended sterilization process | All exposed carriers and packaging components are not bacteriostatic in a worst-case situation | Compliance with 2007 FDA BI guidance and ANSI/AAMI/ISO 11138-1 |
| Holding Time Assessment | A series of sub-lethal exposures and population assays to evaluate the effect of the labeled holding time on the resistance characteristics and spore recovery | The resistance characteristics are not altered significantly over a 7-day hold time prior to incubation. | Compliance with 2007 FDA BI guidance |
| Recovery Protocols, Medium and Incubation Time | To validate the recovery protocols, medium, and a reduced incubation time per 2007 FDA BI guidance and ANSI/AAMI/ISO 11138-1 | Growth of an inoculum of 10-100 spores of Bacillus atrophaeus after being subjected to the sterilization process. | Compliance with 2007 FDA BI guidance and ANSI/AAMI/ISO 11138-1;<br><br>Data generated supports an incubation time of 48 hours for EZTest-Gas biological indicators. |

| | | | |
|---|---|---|---|
| **D-Value Comparison for EZTest-Gas Biological Indicator** | | | |
| D-value | Determine D-value using a fraction negative method | D-values are within 20% of the original stated values for all lots of biological indicators tested. | There is no significant difference in the D-values measured in a vacuum BIER vs. an A-BIER. |
| **Performance Testing for the EOGas 4 Endo-SteriTest** | | | |
| Half Dose Validation | To demonstrate that the EOGas 4 Endo-SteriTest presents a rigorous challenge to the sterilization process | Device is appropriate for monitoring the efficacy of the sterilization process claimed | Partial kill of biological indicators in PCD in half dose cycles, and complete kill in full dose cycles;<br>Biological indicators at the worst-case locations in the endoscope loads are completely inactivated in both half and full dose cycles;<br>EO concentration in the full dose cycles are twice the concentration in the half dose cycles for each endoscope load. |
| Pass/Fail Results from the EOGas 4 Sterilizer | To validate EOGas 4 Endo-SteriTest against the duodenoscope and colonoscope loads indicated for processing in the EOGas 4 sterilizer | Correctly indicate pass/fail in cycles | Data demonstrate the EOGas 4 Endo-SteriTest correctly indicates passed and failed 6-hour gas exposures in the EOGas 4 throughout the stated shelf life. |
| Endpoint Color Stability of the Chemical Indicator | To evaluate the stability of the endpoint color of the chemical indicator on the biological indicator | Stability to provide reasonable assurance of effectiveness | The endpoint green/brown color was stable for at least 28 days when EZTest-Gas BIs were stored at 20-25°C or at 35-39°C after the EOGas 4 sterilization cycles. |
| Shelf Life | To demonstrate the stability of the resistance characteristics and correctly indicate pass/fail in cycles throughout the stated shelf life | Stability of the D-Value and spore population;<br>Correctly indicate pass/fail in cycles | Maintains performance specifications throughout the stated shelf life of 2 years |

## Conclusion:

The conclusions drawn from the nonclinical tests demonstrate that the EOGas 4 Endo-SteriTest is as safe, as effective, and performs as well as or better than the legally marketed EOGas 4 SteriTest (**K151585**).