

510(k) Summary

K192980

Applicant's Name and Address

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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 Process parameters: EO concentration, time, temperature, and relative humidity	Identical
Organism	<i>Bacillus atrophaeus</i> (ATCC 9372)	Identical
Viable Spore Population	$\geq 1.0 \times 10^6$	Identical
Device Design	SCBI 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.	SCBI Identical
	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 Same; Modified for a 6-hour gas exposure used for duodenoscope and colonoscope sterilization
	Purge probe Blue color	Purge probe 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 <i>Bacillus atrophaeus</i> 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 <i>Bacillus atrophaeus</i> 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	≥10 ⁶ microorganisms per unit; 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; Survival/Kill Time: 15 min; 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; 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; Biological indicators at the worst-case locations in the endoscope loads are completely inactivated in both half and full dose cycles; 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; 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**).