November 12, 2020

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

Re: K200334
Trade/Device Name: AN1036 Dosimeter
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: October 26, 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)*
K200334

Device Name
AN1036 Dosimeter

Indications for Use *(Describe)*

AN1036 Dosimeter is a single-use color change chemical indicator. It is calibrated for sterilization temperature and used to verify adequate cumulative ethylene oxide exposure in a 3-hour or 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer manufactured by Andersen Sterilizers, Inc.

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

Table 1. Critical sterilization cycle parameters 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	35-70%	3 hours	3.5 hours
			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
K200334

Applicant's Name and Address

Andersen Sterilizers, Inc.
Establishment Registration Number 3004634710
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 26, 2020

Device

Proprietary Name	AN1036 Dosimeter
Common Name	Indicator, Physical/Chemical Sterilization Process
Classification	Class II (21 CFR 880.2800) Chemical Indicator
Product Code	JOJ

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	AN1087 Dosimeter
510(k) number	**K150645**
Manufacturer	Andersen Sterilizers, Inc.

The predicate AN1087 Dosimeters were cleared for use with 3-hour gas exposures in the EOGas 4 Ethylene Oxide Gas Sterilization system manufactured by Andersen Sterilizers, Inc.

The sterilization time claim of the predicate device was modified in order to indicate the AN1087 Dosimeters for use in 6-hour gas exposures in the EOGas 4 Ethylene Oxide Gas Sterilization System. No modifications were made to the manufacturing method, technology, or intended use.

Device Description

The AN1036 Dosimeter is a single-use chemical indicator for cumulative ethylene oxide exposure. It is an accessory for the EOGas 4 Ethylene Oxide Gas Sterilizer.

The AN1036 Dosimeter contains a proprietary pH indicator in a glass capillary tube that is sealed on one end and mounted on a plastic tray. It is calibrated for a 50°C sterilization temperature and responds to ethylene oxide concentration and sterilization time. With exposure to ethylene oxide, the indicator turns from yellow-orange to a dark blue color from the open end toward the closed end. The extent of the color change is proportional to cumulative ethylene oxide exposure. The cycle-specific calibration marks represent adequate cumulative ethylene oxide exposure to inactivate a 6-Log *Bacillus atrophaeus* biological indicator at the location of the AN1036 Dosimeter after 3-hour gas exposures or at the center of the endoscope lumens after 6-hour gas exposures. The AN1036 Dosimeter is not a replacement for a biological indicator.

Indications for Use

AN1036 Dosimeter is a single-use color change chemical indicator. It is calibrated for sterilization temperature and used to verify adequate cumulative ethylene oxide exposure in a 3-hour or 6-hour gas exposure at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer manufactured by Andersen Sterilizers, Inc.

Critical process parameters for the cycles are summarized in **Table 5-1**.

Table 5-1. Critical sterilization cycle parameters 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
			6 hours	7 hours

Technological Characteristics Comparison

The subject AN1036 Dosimeter is compared to the predicate AN1087 Dosimeter (**K150645**): there is no difference in intended use, design principles, technical characteristics, or performance between the devices.

The difference between the predicate AN1087 and subject AN1036 Dosimeters is the addition of a calibration mark suitable for a 6-hour gas exposure.

A comparison between the indicators is listed in **Table 5-2**.

Table 5-2. Comparison between the subject AN1036 Dosimeter and the predicate AN1087 Dosimeter (**K150645**)

	Predicate AN1087 Dosimeter (K150645)	**Subject AN1036 Dosimeter (K200334)**	**Comparison**
Intended Use	Chemical indicator for cumulative EO exposure in the EOGas 4 Ethylene Oxide Gas Sterilizer	Chemical indicator for cumulative EO exposure in the EOGas 4 Ethylene Oxide Gas Sterilizer	Identical
Design	A pH indicator changes color when exposed to EO; The extent of the color changes is proportional to cumulative EO exposure; Calibrated for use at 50±3°C; One calibration mark for use in 3-hour gas exposures	A pH indicator changes color when exposed to EO; The extent of the color changes is proportional to cumulative EO exposure; Calibrated for use at 50±3°C; Two calibration marks for use in both 3-hour and 6-hour gas exposures	Identical
Technology	Chemical reactions with EO change the pH, and therefore the color, of the indicator ink	Chemical reactions with EO change the pH, and therefore the color, of the indicator ink	Identical
Performance	Indicates cumulative EO exposure	Indicates cumulative EO exposure	Identical
Shelf Life	3 years	3 years	Identical
Endpoint Specifications	Endpoint blue color is stable for 28 days at 20-25°C and 3 days at 50°C.	Endpoint blue color is stable for 28 days at 20-25°C and 4 days at 50°C.	Similar

Summary of Non-clinical Testing:

The AN1036 Dosimeters were validated using applicable tests in:

1) FDA 2003 guideline, "Premarket Notification [510(k)] Submissions for Chemical Indicators: Guidance for Industry and FDA Staff"; and
2) ANSI AAMI ISO 11140-1, "Sterilization of health care products - Chemical Indicators - Part 1: General requirements" (FDA Recognition Number 14-460).

The performance of the AN1036 Dosimeter was characterized in an Andersen Chemical Indicator Evaluator Resistometer as well as in the EOGas 4 Ethylene Oxide Gas Sterilizer using 3- and 6-hour gas exposures at 50°C. The critical parameters to which the AN1036 responds include temperature, time, and ethylene oxide gas concentration in a relative humidity-controlled environment. The AN1036 indicates adequate cumulative EO exposure in the cycle for all validated loads in the EOGas 4 Ethylene Oxide Gas Sterilizer. Using the AN1036 Dosimeter at various stages of shelf life, the distance the blue line travels is stable for a minimum of 28 days after the sterilization cycle when AN1036 Dosimeters are stored at room temperature (20-25°C) and 4 days when stored at 50°C. Real-time shelf life testing with the AN1036 Dosimeter supports a shelf life of 3 years.

Performance testing is summarized in **Table 5-3**.

Table 5-3. Summary of bench tests performed to demonstrate safety and effectiveness of the AN1036 Dosimeter

Test	Purpose	Acceptance Criteria	Results
Chemical Indicator	To validate AN1036 Dosimeter as a chemical indicator per ANSI/AAMI/ISO 11140-1 and FDA Chemical Indicator guidance	Critical parameters with pass/fail criteria; Able to correctly indicate pass/fail results from the EOGas 4 Sterilizer	AN1036 Dosimeters respond to EO concentration, sterilization time, and temperature, at a relative humidity of 35-90%. AN1036 Dosimeters correctly indicate pass/fail in various endoscope loads. A correlation exists between the extent the blue color travels and cumulative EO exposure.
Biocompatibility	To demonstrate the AN1036 Dosimeters are safe to use	Provides reasonable assurance for safety	AN1036 Dosimeter is not a direct or indirect patient-contacting device. None of the major ingredients is hazardous. No chemicals leach out of the AN1036 Dosimeters during the sterilization cycle. Without any additional aeration, the residual EO detected in Dosimeters met ISO 10993-7 requirements.
Endpoint Color Stability	To evaluate the stability of the endpoint color	Stability demonstrates reasonable assurance for effectiveness	Endpoint blue color is stable for 28 days at 20-25°C or 4 days at 50°C after 6-hour gas exposures.
Shelf Life	Evaluate the ability to correctly indicate pass/fail in cycles through the shelf life	Maintains performance specifications throughout the stated shelf life	Data supports claimed shelf life of 3 years

Conclusions:

The conclusions drawn from the nonclinical tests demonstrate that the AN1036 Dosimeter device is as safe, as effective, and performs as well as or better than the legally marketed AN1087 Dosimeter (**K150645**).