November 1, 2017

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

Re: K170439
Trade/Device Name: AN87 Dosimeter
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: September 28, 2017
Received: October 6, 2017

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. 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 (DICE) 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 (DICE) 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,

Michael J. Ryan -S

for Tina Kiang
Acting 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)*
K170439

Device Name
AN87 Dosimeter

Indications for Use *(Describe)*

AN87 Dosimeter is a single-use color change chemical indicator that is calibrated for sterilization temperature and used to verify adequate cumulative ethylene oxide exposure in the 12 hour sterilization cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer manufactured by Andersen Sterilizers, Inc.

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

Table 1. Critical sterilization cycle parameters in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	Temperature	Relative Humidity	Ethylene Oxide Exposure Time	Total Cycle Time
17.6 g ± 5%	20-29°C	35-90%	12 hours	14 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)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K170439 510(k) Summary

5.1 Applicant's Name and Address

Andersen Sterilizers, Inc.
Establishment Registration Number 3004634710
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: September 28, 2017

5.4 Device

Proprietary Name	AN87 Dosimeter®
Common Name	Indicator, Physical/Chemical Sterilization Process
Classification	Class II (21 CFR 880.2800) Chemical Indicator
Product Code	JOJ

5.5 Predicate Device

Device Name	AN1087 Dosimeter®
510(k) number	K150645
Manufacturer	Andersen Sterilizers, Inc.

The predicate AN1087 Dosimeters are approved for use with the EOGas 4® Ethylene Oxide Gas Sterilization system manufactured by Andersen Sterilizers, Inc.

The sterilization temperature and time claims of the predicate devices were modified in order to indicate the AN87 Dosimeters for use in the Anprolene AN75 Ethylene Oxide Gas Sterilization System. No modifications were made to the manufacturing method, technology, or intended use.

5.6 Device Description

The AN87 Dosimeter is a single-use chemical indicator for cumulative ethylene oxide exposure. It is an accessory for the Anprolene AN75 Ethylene Oxide Gas Sterilizer.

The AN87 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 20-29°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 the cumulative ethylene oxide exposure. The calibration mark represents adequate cumulative ethylene oxide exposure to inactivate a 6-Log *Bacillus atrophaeus* biological indicator at the location of the AN87 Dosimeter. The AN87 Dosimeter is not a replacement for a biological indicator.

5.7 Indications for Use

AN87 Dosimeter is a single-use color change chemical indicator that is calibrated for sterilization temperature and used to verify adequate cumulative ethylene oxide exposure in the 12 hour sterilization cycle at 20-29°C in the Anprolene AN75 Ethylene Oxide Gas Sterilizer manufactured by Andersen Sterilizers, Inc.

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

Table 5-1. Critical sterilization cycle parameters in the Anprolene AN75 Ethylene Oxide Gas Sterilizer

Ethylene Oxide	Temperature	Relative Humidity	Ethylene Oxide Exposure Time	Total Cycle Time
17.6 g ± 5%	20-29°C	35-90%	12 hours	14 hours

5.8 Substantial Equivalence Comparison

The AN87 Dosimeter is substantially equivalent to the predicate device - AN1087 Dosimeter (K150645): there is no difference in intended use, design, technical characteristics, or performance between the devices. The differences between the AN1087 and AN87 Dosimeters are the sterilization temperature and time in the indications for use; the differences raise no issues related to safety or effectiveness because the devices are calibrated and validated for the sterilization temperatures and times claimed. A comparison between the indicators is listed in **Table 5-2**.

Table 5-2. Comparison between AN87 Dosimeter and the predicate AN1087 Dosimeter

	Predicate AN1087 Dosimeter (K150645)	Subject AN87 Dosimeter	Comparison
Intended Use	Chemical indicator for cumulative EO exposure in the EOGas 4 sterilizer	Chemical indicator for cumulative EO exposure in the Anprolene AN75 sterilizer	Substantially Equivalent
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.	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 20-29°C.	Substantially Equivalent
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	Accurately indicates cumulative EO exposure	Accurately indicates cumulative EO exposure	Equivalent
Shelf Life	3 years	3 years	Equivalent
Endpoint Specifications	Endpoint blue color is stable for at least 28 days at 20-25°C	Endpoint blue color is stable for at least 28 days at 20-25°C and 3 days at 50°C	Equivalent

5.9 Performance Testing

The AN87 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) AAMI/ANSI/ISO 11140-1, "Sterilization of health care products - Chemical Indicators - Part 1: General requirements" (FDA Recognition Number 14-459).

The performance of the AN87 Dosimeter was characterized in an Andersen Chemical Indicator Evaluator Resistometer as well as in an Anprolene AN75 Ethylene Oxide Gas Sterilizer using the 12 hour cycle at 20-29°C. The critical parameters to which the AN87 responds include temperature, time, and gas concentration in a relative humidity controlled environment. The AN87 indicates adequate cumulative EO exposure in the cycle for all validated loads in the Anprolene AN75 sterilizer. The AN87 performance parallels the performance of a 6-Log *Bacillus atrophaeus* biological indicator. A strong correlation is observed between cumulative EO exposure and the distance the blue color travels in the AN87 Dosimeter. Using the AN87 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 AN87 Dosimeters are stored at room temperature (20-25°C). Real-time shelf stability testing with the AN87 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 AN87 Dosimeter

Test	Description	Result
Functionality	1) Critical parameters include temperature, time, and gas concentration at a relative humidity of 35-90%; 2) Performance parallels that of a biological indicator; 3) A correlation exists between the extent the blue color travels and cumulative EO exposure.	Pass
Biocompatibility	Not direct or indirect patient-contacting devices; Non-toxic ingredients; Provides reasonable assurance for safety	Pass
Endpoint Color Stability	Stable for at least 28 days at 20-25°C; Stability demonstrates reasonable assurance for effectiveness	Pass
Shelf Life	Maintains performance specifications throughout the stated shelf life of 3 years	Pass

The nonclinical tests demonstrate that the AN87 Dosimeter, used in the Anprolene AN75 Ethylene Oxide Gas Sterilizer, is as safe, as effective, and performs as well as the legally marketed device, the AN1087 Dosimeter (K150645) used in the EOGas 4 Ethylene Oxide Gas Sterilizer.