DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 19, 2015

Andersen Sterilizers, Inc.
William K. Andersen, BE, MD, FAAOS
President
3154 Caroline Dr
Haw River, NC 27258

Re: K150645
Trade/Device Name: AN1087 Dosimeter
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory Class: II
Product Code: JOJ
Dated: October 20, 2015
Received: October 22, 2015

Dear Dr. 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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
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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)*
K150645

Device Name
AN1087 Dosimeter

Indications for Use *(Describe)*

AN1087 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 3 hour sterilization cycle at 50°C in the Andersen Sterilizers EOGas 4 Ethylene Oxide Gas Sterilizer.

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

Table 1. Critical parameters for the 3 hour cycle 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

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)*

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510(k) Summary

5.1 Applicant's Name and Address		Andersen Sterilizers, Inc. 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		October 20, 2015
5.4 Device	Proprietary Name	AN1087 Dosimeter®
	Common Name	Indicator, Physical/Chemical Sterilization Process
	Classification	Class II (21 CFR 880.2800) Chemical Indicator
	Product Code	JOJ

The AN1087 Dosimeter is part of the refill kit for the EOGas 4 Ethylene Oxide Gas Sterilizer registered with the US Environmental Protection Agency (EPA #69340-7).

5.5 Pre-amendment Device

Device Name	AN87 Dosimeter®
510(k) number	NA
Manufacturer	Andersen Sterilizers, Inc.

The AN87 Dosimeter was legally marketed prior to the Medical Device Act, and has been in continuous use with Andersen ethylene oxide sterilization systems since the early 1970's. No 510(k) number exists for the AN87 Dosimeter.

The purpose for this submission is to modify the sterilization temperature claim of the pre-amendment device - AN87 Dosimeter. No modifications were made to the technology or intended use.

5.6 Device Description

The AN1087 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 AN1087 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 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 AN1087 Dosimeter. The AN1087 Dosimeter is not a replacement for a biological indicator.

5.7 Indications for Use

AN1087 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 3 hour sterilization cycle at 50°C in the Andersen Sterilizers EOGas 4 Ethylene Oxide Gas Sterilizer.

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

Table 5-1. Critical parameters for the 3 hour cycle 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

5.8 Substantial Equivalence Comparison

The AN1087 Dosimeter is substantially equivalent to the pre-amendment device - AN87 Dosimeter, because there is no difference in intended use, design, technical characteristics, and performance between them. The slight difference between two Dosimeters is the sterilization temperature indicated for use, but the difference raises no issues related to safety or effectiveness because they are calibrated and validated at the sterilization temperatures claimed. A comparison between the indicators is listed in **Table 5-2**.

Table 5-2. Comparison between AN1087 Dosimeter and the pre-amendment device

	AN87 Dosimeter	**AN1087 Dosimeter**	**Comparison**
Intended Use	Chemical indicator for cumulative EO exposure	Chemical indicator for cumulative EO exposure	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 23±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 50±3°C.	Equivalent
Technology	Chemical reactions with EO changes the pH and thus the color of the indicator ink	Chemical reactions with EO changes the pH and thus the color of the indicator ink	Equivalent
Performance	Accurately indicated EO exposure;	Accurately indicated EO exposure;	Equivalent

5.9 Performance Testing

The performance of the AN1087 Dosimeter was characterized in an Andersen Chemical Indicator Evaluator Resistometer as well as in an EOGas 4 Ethylene Oxide Gas Sterilizer using the 3 hour cycle at 50°C. Performance testing is summarized in **Table 5-3**.

Table 5-3. Summary of bench tests performed to demonstrate safety and effectiveness of the AN1087 Dosimeter

Test	**Description**	**Result**
Functionality	1) Critical parameters include temperature, time, and gas concentration under a relative humidity of 35-90%; 2) Performance parallels that of a biological indicator; 3) A correlation between the extent of the blue color formed and the cumulative EO exposure; 4) A correlation between the measured vs. calculated 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 and 3 days at 50°C; Stability demonstrates reasonable assurance for effectiveness	Pass
Shelf Life	Maintains performance specifications throughout the stated shelf life of 3 years	Pass

In conclusion, the bench performance testing demonstrates that the AN1087 Dosimeter performs as intended to indicate cumulative EO exposure, and provides reasonable assurance of safety and effectiveness, equivalent to the legally marketed pre-amendment device, the AN87 Dosimeter.