DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 18, 2015

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

Re: K150644
Trade/Device Name: AN85/AN86 EO Indicators
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization process indicator
Regulatory Class: Class II
Product Code: JOJ
Dated: October 20, 2015
Received: October 22, 2015

Dear Dr. William K. 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 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 Industry and Consumer Education 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,
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)*
K150644

Device Name
AN85/AN86 EO Indicators

Indications for Use *(Describe)*

The AN85/AN86 EO Indicators are single-use Class 1 process indicators used to distinguish between processed and unprocessed packaged medical devices, through a visible color change from yellow-green to blue. They are intended for the 3 hour sterilization cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer manufactured by Andersen Sterilizers, Inc. 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K150644

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

November 17, 2015

5.4 Device

Proprietary Name	AN85/AN86 EO Indicators
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	VERIFY EO Valueline Chemical Indicator
510(k) number	K991418
Manufacturer	Steris Corporation

5.6 Device Description

AN85/AN86 EO Indicators are adhesive-backed Class 1 process indicators for ethylene oxide sterilization that conform to AAMI/ANSI/ISO 11140-1.

AN85/AN86 EO Indicators contain a pH indicator. The pH indicator ink is printed in dots on the AN85 and in stripes on the AN86. The indicator ink is laminated between two layers of plastic material and changes color from yellow-green to blue by chemical reactions when exposed to ethylene oxide.

5.7 Indications for Use

The AN85/AN86 EO Indicators are single-use Class 1 process indicators used to distinguish between processed and unprocessed packaged medical devices, through a visible color change from yellow-green to blue. They are intended for the 3 hour sterilization cycle at 50°C in the EOGas 4 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 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 Technological Characteristics

AN85/AN86 EO Indicators contain a proprietary pH indicator which changes color by chemical reactions when exposed to ethylene oxide, allowing differentiation of ethylene oxide processed vs. unprocessed devices.

5.9 Performance Testing

The performance of AN85/AN86 EO Indicators was characterized in a Chemical Indicator Evaluator Resistometer (CIER) as well as in an EOGas 4 Ethylene Oxide Gas Sterilizer using the 3 hour cycles at 50°C. Performance testing is summarized in **Table 5-2**.

Table 5-2. Summary of bench tests performed to demonstrate safety and effectiveness of AN85/AN86 EO Indicators

Test	Description	Result
Functionality	1) Critical parameters include temperature, time, and gas concentration under a relative humidity of 35-90%; 2) ISO 11140-1 Class 1 process indicator; 3) Indicate EO exposure in the CIER and in the EOGas 4 sterilizer.	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 12 months at 20-25°C and 3 months at 50°C; Stability demonstrates reasonable assurance for effectiveness	Pass
Shelf Life	Maintains performance specifications throughout the shelf life. For storage, AN85/AN86 indicators should be kept away from EO or products that affect pH such as acids or alkalis, and in an environment of 20-30°C and 30-50% relative humidity. Under the conditions, AN85/AN86 indicators have a shelf life of 2 years from date of manufacture.	Pass

The bench studies demonstrate that AN85/AN86 EO Indicators perform as intended to indicate that the devices have been exposed to ethylene oxide, and perform as safely and effectively as the legally marketed predicate device.

5.10 Device Comparison

AN85/AN86 EO Indicators are substantially equivalent to the VERIFY EO Valueline Chemical Indicator (K991418). Both the subject and predicate indicators have the same intended use, design, and technical characteristics. The difference in endpoint color changes due to different pH indicators used does not raise different questions of safety and effectiveness. A comparison between the indicators is listed in **Table 5-3**.

Table 5-3. Comparison between AN85/AN86 EO Indicators and the predicate device

	VERIFY EO Valueline Chemical Indicator	**AN85/AN86 EO Indicators**	**Comparison**
Intended Use	Process indicator to indicate exposure to EO	Process indicator to indicate exposure to EO	Same
	Insert labels	Adhesive-backed labels	AN85/AN86 may be used to secure wrapping materials
Sterilization Method	Traditional EO sterilizer 100% and blended EO process	The EOGas 4 sterilizer 100% EO process 3 hr cycles at 50°C	Do not affect safety or effectiveness
Design	Indicator changes color when exposed to EO	Indicator changes color when exposed to EO	Equivalent
Indicator Agent	pH indicator	pH indicator	Equivalent
Device Materials	Paper	Plastic films	AN85/AN86 : plastic layer above and below the ink prevents direct contact with the ink
Endpoint Color Change	Orange to red color	Yellow-green to blue color	Equivalent
Technology	Chemical reactions with EO changes the pH and the color of the indicator ink	Chemical reactions with EO changes the pH and the color of the indicator ink	Equivalent
Performance	Correctly indicated EO exposure; Class 1 process indicator.	Correctly indicated EO exposure; Class 1 process indicator.	Equivalent

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:
Based on the intended use, technological characteristics, performance data, and nonclinical tests performed, the subject AN85/AN86 EO Indicators are substantially equivalent to, and are as safe and as effective as, the legally marketed predicate device, VERIFY EO Valueline Chemical Indicator, cleared under K991418.