U.S. FOOD & DRUG ADMINISTRATION

October 30, 2017

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

Re: K170426
Trade/Device Name: AN85/AN86 EO Indicators
Regulation Number: 21 CFR 880.2800
Regulation Name: Sterilization Process Indicator
Regulatory 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, Ph.D.
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)*
K170426

Device Name
AN85/AN86 EO Indicators

Indications for Use *(Describe)*

AN85/AN86 EO Indicators are single-use Type 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 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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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."*

K170426

## 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 | 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 | AN85/AN86 EO Indicators |
| 510(k) number | K150644 |
| Manufacturer | Andersen Sterilizers, Inc. |

The predicate AN85 and AN86 EO Indicators (K150644) are approved for use with the EOGas 4® Ethylene Oxide Gas Sterilization system manufactured by Andersen Sterilizers, Inc.

In this submission, the sterilization temperature and time claims of the predicate devices were modified in order to indicate the AN85 and AN86 EO Indicators 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

AN85/AN86 EO Indicators are adhesive-backed Type 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

AN85/AN86 EO Indicators are single-use Type 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 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 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 Anprolene AN75 Ethylene Oxide Gas Sterilizer using the 12 hour cycle at 20-29°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 at a relative humidity of 35-90%;<br>2) ISO 11140-1 Type 1 process indicator;<br>3) Indicate EO exposure in the CIER and in the Anprolene AN75 sterilizer. | Pass |
| Biocompatibility | Not direct or indirect patient-contacting devices;<br>Non-toxic ingredients;<br>Provides reasonable assurance for safety. | Pass |
| Endpoint Color Stability | Stable for at least 12 months at 20-25°C and 30-50% relative humidity away from direct sunlight;<br>Stability demonstrates reasonable assurance for effectiveness. | Pass |
| Shelf Life | Maintains performance specifications throughout the shelf life of 2 years. | 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, the AN85/AN86 EO Indicators (K150644).

5.10 Device Comparison

AN85/AN86 EO Indicators used in the Anprolene AN75 Sterilizer are substantially equivalent to the AN85/AN86 EO Indicators (K150644) used in the EOGas 4 sterilizer. Both the subject and predicate indicators have the same intended use, design, and technical characteristics. A comparison between the indicators is listed in **Table 5-3**.

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

| | **Predicate AN85/AN86 EO Indicators (K150644)** | **Subject AN85/AN86 EO Indicators** | **Comparison** |
|---|---|---|---|
| Intended Use | Process indicator to indicate exposure to EO | Process indicator to indicate exposure to EO | Identical |
| | Adhesive-backed labels | Adhesive-backed labels | Identical |
| Sterilization Method | EOGas 4 sterilizer;<br>100% EO process;<br>3 hr EO exposure at 50±3°C | Anprolene AN75 sterilizer;<br>100% EO process;<br>12 hr EO exposure at 20-29°C | Difference does not alter safety or effectiveness |
| Design | Indicator changes color when exposed to EO | Indicator changes color when exposed to EO | Identical |
| Indicator Agent | pH indicator | pH indicator | Identical |
| Device Materials | Plastic films;<br>Plastic layer above and below the ink prevents direct contact with the ink. | Plastic films;<br>Plastic layer above and below the ink prevents direct contact with the ink. | Identical |
| Endpoint Color Change | Yellow-green to blue color | Yellow-green to blue color | Identical |
| Technology | Chemical reactions with EO change the pH and the color of the indicator ink. | Chemical reactions with EO change the pH and the color of the indicator ink. | Identical |
| Performance | Type 1 process indicator | Type 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, the AN85/AN86 EO Indicators used in the EOGas 4 sterilization system, cleared under K150644.