



Food and Drug Administration  
10903 New Hampshire Avenue  
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November 18, 2015

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

Re: K152058

Trade/Device Name: Tyvek Sterilization Pouches With Chevron Seal  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: Class II  
Product Code: FRG  
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 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" (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 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

## Indications for Use

510(k) Number (if known)

K152058

Device Name

Tyvek® Sterilization Pouches with Chevron Seal

Indications for Use (Describe)

The Tyvek Sterilization Pouches with Chevron Seal are intended to be used to enclose medical devices that are to be sterilized in a single pouch configuration at a healthcare facility. They are used in the 3 hour sterilization cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer.

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

Table 1. Critical parameters for the 3 hour cycle in the EOGas 4 Ethylene Oxide Gas Sterilizer

EO Amount	Temperature	Relative Humidity	EO Exposure Time	Total Cycle Time
17.6 g ± 5%	50°C ± 3°C	35-90%	3 hours	3.5 hours

The 3 hour cycle in the EOGas 4 Ethylene Oxide Gas Sterilizer has been validated to sterilize a load of up to 24 lbs of metal surgical instruments or 7 lbs of plastic devices (combined weight of pouched devices and tray).

The product codes for Tyvek Sterilization Pouches are listed in Table 2.

Table 2. Product codes for Tyvek Sterilization Pouches

Product Type	Self Seal	Heat Seal	Tubing		
Product Codes	TLP-030	TLP-031	TLP-033	TLP-058	TLP-059

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

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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.”*

**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 | Tyvek® Sterilization Pouches with Chevron Seal<br>TLP-030, TLP-031, TLP-033, TLP-058, TLP-059 |
| Common Name      | Sterilization Pouch   |
| Classification   | Class II (21 CFR 880.6850)  |
| Product Code     | FRG   |
- 5.5 Predicate Device
- |               |   |
|---------------|---|
| Device Name   | Tyvek Sterilization Pouches with Chevron Seal |
| 510(k) number | K831425                                       |
| Manufacturer  | Ancor Flexibles                               |

This 510(k) submission modifies the indications for use of the predicate device in order to include it as a component in the EOGas 4® ethylene oxide sterilization system. No modifications were made to the technology or intended use.

**5.6 Device Description**

The Tyvek Sterilization Pouches with Chevron Seal are constructed from an uncoated Tyvek backing of fine, continuous high-density polyethylene (HDPE) fibers, with front material consisting of a clear, laminated polyethylene terephthalate (PET) / low density polyethylene (LDPE) or LDPE-ethylene-vinylacetate copolymers (EVA) film. They are used to enclose medical devices that are to be sterilized by a healthcare provider in the 3 hour sterilization cycle at 50°C in an EOGas 4 Ethylene Oxide Gas Sterilizer. Devices are inserted into the pouches and sealed. The self-seal pouch permits sealing of the pouch without heat-sealing equipment, while the heat sealed pouches are heat sealed prior to the cycle. After completion of the sterilization process, the pouches maintain sterility of the enclosed medical devices for at least 3 months (90 days) or until used.

The AN85/AN86 EO Indicators, when placed on the outside of the sterilization pouches, indicate ethylene oxide exposure and offer a convenient way to verify processing in the sterilization

cycle. The color of the AN85/AN86 EO Indicators changes from yellow-green to blue after exposure to ethylene oxide.

### 5.7 Indications for Use

The Tyvek Sterilization Pouches with Chevron Seal are intended to be used to enclose medical devices that are to be sterilized in a single pouch configuration at a healthcare facility. They are used in the 3 hour sterilization cycle at 50°C in the 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

The 3 hour cycle in the EOGas 4 Ethylene Oxide Gas Sterilizer has been validated to sterilize a load of up to 24 lbs of metal surgical instruments or 7 lbs of plastic devices (combined weight of pouched devices and tray).

The product codes for Tyvek Sterilization Pouches are listed in **Table 5-2**.

**Table 5-2.** Product codes for Tyvek Sterilization Pouches

Product Type	Self-Seal		Heat Seal	Tubing	
Product Codes	TLP-030	TLP-031	TLP-033	TLP-058	TLP-059

### 5.8 Device Comparison

The technological characteristics of the Tyvek Sterilization Pouches with Chevron Seal are identical to the predicate device - both are intended for the same use, use the same technology, and are designed in the same way.

The Tyvek Sterilization Pouches with Chevron Seal differ from the predicate device in the sterilization cycles used. The difference raises no issues related to safety or effectiveness of the subject device in the sterilization cycle. A comparison between the devices is listed in **Table 5-3**.

**Table 5-3.** Device Comparison

Elements	Predicate Device: Tyvek Sterilization Pouches	Subject Device: Tyvek Sterilization Pouches
510(k) Number	K831425	K152058
Intended Use	To enclose medical devices, allow sterilization of the enclosed devices, and maintain sterility of the enclosed devices	Identical

Indications for Use	To be used in ethylene oxide sterilization systems	The Tyvek Sterilization Pouches with Chevron Seal are intended to be used to enclose medical devices that are to be sterilized in a single pouch configuration at a healthcare facility. They are used in the 3 hour sterilization cycle at 50°C in the EOGas 4 Ethylene Oxide Gas Sterilizer. The 3 hour cycle in the EOGas 4 Ethylene Oxide Gas Sterilizer has been validated to sterilize a load of up to 24 lbs of metal surgical instruments or 7 lbs of plastic devices (combined weight of pouched devices and tray).
Design	Adhesive laminated film is a clear, high strength material; Uncoated Tyvek is compatible with EO sterilization, resistant to microbial penetration, and resistant to puncture	Identical
Pouch Types	Self-seal pouch; Heat seal pouch; Heat seal tubing	Identical
Device Construction	Self-seal and heat seal pouches: front and back materials are heat sealed together on three sides; fourth side (end) remains open for filling; end is sealed by heat (heat seal pouches) or by removing protective liner strip, folding along the pre-fold, and pressing to the film (self-seal pouches). Heat seal tubing: front and back materials are heat sealed together on two sides; two ends are open for selecting size and filling; ends are sealed by heat.	Identical
Materials	Clear laminated PET/LDPE or LDPE-EVA film (front) and uncoated HDPE Tyvek (back)	Identical
Configuration in Load	Single pouch configuration	Identical
Shelf Life	5 years from date of manufacture	Identical
Biocompatibility	Materials and biological evaluations (Agar Diffusion Test, Cytotoxicity Test) meet ISO 11607-1 requirements	Materials and biological evaluations (Agar Diffusion Test, Cytotoxicity Test) meet ISO 11607-1 requirements
Maintenance of Sterility	Tyvek pouches are capable of maintaining sterility for at least 5 years	Sterility is maintained for at least 3 months (90 days) after processing in an EOGas 4 sterilizer
Aeration Time	≥ 6 hours	≥ 6 hours
Package Integrity	Seal strength, microbial barrier, burst, and peel open characteristics meet ISO and ASTM requirements	Seal strength, microbial barrier, burst, and peel open characteristics meet ISO and ASTM requirements

## 5.9 Performance Testing

Performance testing was conducted to show that the Tyvek Sterilization Pouches with Chevron Seal perform as intended to allow sterilization of the enclosed medical device. Sterilization efficacy testing demonstrated a 12-Log reduction and a sterility assurance level of  $10^{-6}$  using the overkill method and half cycle or half dose validation methods under worst case conditions. The Tyvek Sterilization Pouches with Chevron Seal also maintain sterility of the enclosed device as intended. Shelf life studies demonstrated sterility maintenance for up to 5 years after completion of an ethylene oxide sterilization process. The performance of the Tyvek Sterilization pouches is summarized in **Table 5-4**.

**Table 5-4.** Summary of bench tests performed to demonstrate safety and effectiveness of the Tyvek Sterilization Pouches

Test	Description	Results
<b>Compliance to ISO 11607-1</b>		
Package Integrity	Seal strength performance characteristics were maintained for the manufactured seal. Microbial Barrier: the contents of pouches were sterile when the processed pouches were subjected to the microbial aerosol challenge test. Burst: ability to withstand the internal pressurization was maintained. Peel open characteristics were maintained.	Meet ISO and ASTM requirements
Material Compatibility	Seal strength test, microbial barrier properties, burst test, and peel open test were studied to demonstrate material compatibility characteristics of the Tyvek Sterilization Pouches	Pass
Biocompatibility	Not direct patient-contacting devices; Materials are non-toxic, FDA compliant, and meet ISO 11607-1 requirements; Biological evaluations meet acceptable criteria; Provides reasonable assurance for safety	Pass
Shelf Life	Physical properties and microbial barrier of the processed Tyvek Pouches was verified at the end of shelf life of 5 years; Stability demonstrates reasonable assurance for effectiveness	Pass
<b>Performance in the EOGas 4 Cycle</b>		
Sterilant Penetration	The sterilant penetrated the pouch under worst case half-dose conditions and inactivated 6-Log biological indicators	Allow a sterility assurance level of $10^{-6}$ for the sterilization cycle
Maintenance of Package Integrity	Sterility was maintained for at least 3 months (90 days) after the EOGas 4 processing.	Pass



## 5.10 Conclusion

Based on the intended use, technological characteristics, performance data and nonclinical tests performed, the subject Tyvek Sterilization Pouches with Chevron Seal is substantially equivalent to the predicate device - Tyvek Sterilization Pouches with Chevron Seal (K831425).