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STERIS®

NOV 19 2010

510(k) Summary
For
Vis-U-All Low Temperature Tyvek Sterilization Pouch for Ethylene Oxide Sterilization

STERIS Corporation
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Summary Date: November 19, 2010

1. **Device Name**

Trade Name:	Vis-U-All Low Temperature Tyvek Sterilization Pouch for Ethylene Oxide Sterilization
Common/usual Name:	Sterilization Pouch
Classification Name:	Sterilization Wrap (21 CFR 880.6850)
Product Code:	KCT

2. **Predicate Device**

- Vis-U-All Self Seal Pouch (K070765)
- Vis-U-All Heat Seal Pouch and Tubing (K071087)

3. **Description of Device**

The proposed Vis-U-All Low Temperature Tyvek Sterilization Pouch for Ethylene Oxide is a Tyvek/plastic film sterilization containment pouch designed for devices to be sterilized by the health care provider using ethylene oxide (ETO). The proposed pouch is available as a self seal pouch, a heat seal pouch, or heat seal tubing.

4. **Intended Use**

The Vis-U-All Low Temperature Tyvek Sterilization Pouch for ethylene oxide has been qualified by STERIS Corporation as suitable for use by health care providers to enclose and seal other medical devices to be sterilized by ethylene oxide (ETO). The Vis-U-All Low Temperature Tyvek Sterilization Pouch for ethylene oxide is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use.

Pouch and Tubing Sizes for STERIS Vis-U-All Low Temperature Products

STERIS Part #	Type	Size (inches)
875037	Pouch, Heat Seal, Tyvek (low temp)	3 x 7
875049		4 x 9
875412		4 x 12
875422		4 x 22
875610		6 x 10
875812		8 x 12
875115		10 x 15
875118		12 x 18
876037	Pouch, Self Seal, Tyvek (low temp)	3 x 7
876049		4 x 9
876412		4 x 12
876422		4 x 22
876610		6 x 10
876812		8 x 12
876115		10 x 15
876118		12 x 18
872031	Tubing, Heat Seal, Tyvek (low temp)	3" x 100 ft
872041		4" x 100 ft
872061		6" x 100 ft
872091		9" x 100 ft
872141		14" x 100 ft

The following are the validation test conditions:

- 1 hour exposure; at 130(±5) °F*, >30% RH using 100% ETO (750-790 mg/L);
- 4.5 hour exposure; at 100(±5) °F*, >30% RH using 100% ETO (750-790 mg/L);

* ±5 °F is during sterilization phase following an equilibration period of 10% of exposure time.

The ethylene oxide process indicator is intended to be used by a health care provider with the Vis-U-All Low Temperature Tyvek Sterilization Pouches to distinguish between processed and unprocessed units.

5. **Description of Safety and Substantial Equivalence**

The Vis-U-All Low Temperature Tyvek Sterilization Pouch models have been qualified by STERIS Corporation as suitable for use by health care providers to enclose and seal other medical devices to be sterilized using ethylene oxide. The predicates, Vis-U-All Self Seal Pouch (K070765) and Vis-U-All Heat Seal Pouch and Tubing (K071087) are also intended to enclose and seal medical devices to be sterilized. The proposed device's intended use is identical to the predicates, exceptingh thelow temperature sterilization modality to which the pouch is exposed: ethylene oxide (ETO) instead of hydrogen peroxide (VHP).

The proposed device is identical to the predicate devices in terms of physical and chemical properties, configurations and dimensions, air permeance and percent of surface perforations. The material composition of the proposed and predicate device is identical with the exception of the addition of an ISO 11140 Class 1 compliant, ethylene oxide chemical indicator on the proposed device.

As described in the next section, performance testing of the Vis-U-All Low Temperature Tyvek Sterilization Pouch for Ethylene Oxide demonstrated that the proposed product is qualified for use with ethylene oxide (ETO) sterilization and is as safe, as effective, and performs the same as the predicate devices.

6. **Performance Testing**

The following table summarizes the non-clinical testing performed for both indicated sterilization cycles to demonstrate that the Vis-U-All Low Temperature Tyvek Sterilization Pouch for Ethylene Oxide is safe and effective. The performance testing has demonstrated that the proposed device is substantially equivalent to its predicates and raises no new questions of safety or effectiveness.

Testing	Results
Sterilant Penetration	***PASS*** Testing demonstrated that ethylene oxide can effectively penetrate the pouches to sterilize the load.
Event Related Sterility Maintenance	***PASS*** All packs processed in an ethylene oxide sterilizer and subjected to accelerated aging and handling maintained their performance (strength and microbial resistance).
Microbial Barrier Properties	***PASS*** No microbial growth occurred on test articles or negative control pouches. Test articles from positive control pouches demonstrated microbial growth
Tensile / Tear / Puncture Resistance / Seal Peel Strength	***PASS*** The differences in tensile properties (elongation, breaking force) of processed and unprocessed Tyvek and plastic samples were not statistically significant. All processed but un-aged pouches resulted in clean peels and all processed pouches had acceptable burst strength, indicating that ethylene oxide sterilization does not compromise pouch sealing.
Cytotoxicity	***PASS*** Following ethylene oxide sterilization, the Vis-U-All Low Temperature Tyvek Pouch/Tubing plastic and Tyvek were not cytotoxic.
Sterilant Residues	***PASS*** Following sterilization and aeration, pouch materials were confirmed to not retain harmful levels of ethylene oxide or its byproducts as outlined in ISO 10993-7:1995.
Chemical Indicator Class 1 Compliance	***PASS*** Chemical Indicators were validated against the ethylene oxide process indicator requirements of ANSI/AAMI/ISO 11140-1:2005
Chemical Indicator Toxicity	***PASS*** The indicator ink on its substrate– either exposed to ethylene oxide or unexposed - is not cytotoxic per the methodology and limits defined in ANSI/AAMI/ISO10993-5:1999.
Chemical Indicator Post-Processed Color Stability	***PASS*** The post-processed chemical (process) indicator color is stable, after exposure to ETO sterilization conditions, for at least one year of storage at ambient conditions.
Simulated Use	***PASS*** All criteria of the study were met, demonstrating that, ethylene oxide can penetrate through the Vis-U-All Low Temperature Tyvek Pouch and Tubing to sterilize loads.
Process Indicator End Point Stability – Aged Vis-U-All Tyvek pouches	***PASS*** The chemical indicator on Vis-U-All Low Temperature Tyvek Pouches stored at warehouse conditions still meet performance criteria.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Marcia Benedict
Director, Regulatory Affairs
Steris Corporation
5960 Heisley Road
Mentor, Ohio 44060

NOV 19 2010

Re: K092745
Trade/Device Name: Vis-U-All Low Temperature Tyvek Sterilization Pouch with Ethylene Oxide Process Indicator
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: November 11, 2010
Received: November 12, 2010

Dear Ms. Benedict:

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.

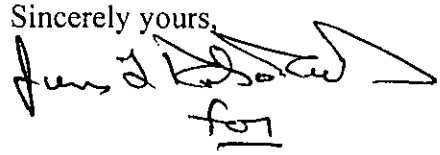
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

NOV 1 9 2010

510(k) Number (if known): **K092745**

Device Name: **Vis-U-All Low Temperature Tyvek Sterilization Pouch with Ethylene Oxide Process Indicator**

Indications For Use:

The Vis-U-All Low Temperature Tyvek Sterilization Pouch for ethylene oxide has been qualified by STERIS Corporation as suitable for use by health care providers to enclose and seal other medical devices to be sterilized by ethylene oxide (ETO). The Vis-U-All Low Temperature Tyvek Sterilization Pouch for ethylene oxide is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use.

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(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: _____

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Prescription Use _____ AND/OR Over-The-Counter Use ____X___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K092745