STERIS®

JUL 2 2 2014

K140487

510(k) Summary
For
Vis-U-All Low Temperature Sterilization Pouch/Tubing

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Summary Date: June 20, 2014

1. Device Name

Trade Name:	Vis-U-All Low Temperature Sterilization Pouch/Tubing
Common/usual Name:	Sterilization pouch
Classification Name:	Sterilization wrap (21 CFR 880.6850 Product Code FRG). Class II

2. Predicate Devices

K090371 - Vis-U-All Low Temperature Tyvek Sterilization Pouch for V-PRO 1 Sterilization System

3. Description of Device

The proposed Vis-U-All Low Temperature Sterilization Pouch/Tubing is a Tyvek/plastic film sterilization containment pouch designed for devices to be sterilized by the health care provider in the V-PRO 60 Low Temperature Sterilization System. The proposed device is available as a self seal pouch, a heat seal pouch, or heat seal tubing.

The purpose of this submission is to demonstrate the Vis-U-All Low Temperature Sterilization Pouch/Tubing is substantially equivalent to the predicate device in terms of safety and effectiveness

4. Intended Use

The Vis-U-All Low Temperature Sterilization Pouches/Tubing are sterilization containment pouches for use by health care providers to enclose medical devices to be sterilized in Lumen and Non Lumen Cycles in the V-PRO 60 Low Temperature Sterilization System. The pouches are intended to maintain the sterility of the enclosed devices until used.

Pouches are intended to contain devices in such a manner as to leave a minimum of one inch between the devices and seal on all sides. Devices with stainless steel lumens and the following minimum internal diameter (ID) and maximum length can be processed in Vis-U-All Low Temperature Sterilization Pouch/Tubing using the Lumen Cycle.

- single or dual lumen devices
  - 0.77 mm ID and 410 mm in length
- triple lumen devices
  - 1.2 mm ID and 275 mm in length

- 1.8 mm ID and 310 mm in length

or

- 2.8 mm ID and 317 mm in length

5. Available Sizes / Configurations

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

6. Comparison of Technological Characteristics

Characteristic	Proposed	Predicate	Comparison
Materials of Construction	Tyvek and plastic	Tyvek and plastic	Same
Types	Self Seal, Heat Seal, Tubing	Self Seal, Heat Seal, Tubing	Same
Chemical Indicator	Ethylene Oxide Process Chemical Indicator Printed on both sides of Tyvek	Ethylene Oxide Process Chemical Indicator Printed on both sides of Tyvek	Same
Intended Use	The Vis-U-All Low Temperature Sterilization Pouch/Tubing is a sterilization containment pouch for use by health care providers to enclose medical devices to be sterilized and maintains the sterility of the enclosed devices until used.	The Vis-U-All Low Temperature Sterilization Pouch/Tubing is a sterilization containment pouch for use by health care providers to enclose medical devices to be sterilized and maintains the sterility of the enclosed devices until used.	Same
Indications for Use	The Vis-U-All Low Temperature Sterilization Pouch/Tubing is a sterilization containment pouch for use by health care providers to enclose medical devices to be sterilized in Lumen and Non Lumen Cycles in the V-PRO 60 Low Temperature Sterilization System. The pouch maintains the sterility of the enclosed devices until used. Pouches are intended to contain devices in such a manner as to leave a minimum of one inch between the devices and seal on all sides. Devices with stainless steel lumens and the following minimum internal diameter (ID) and maximum length can be processed in Vis-U-All Low Temperature Sterilization Pouch/Tubing using the Lumen cycle. o <u>single or dual lumen devices</u> ▪ 0.77 mm ID and 410 mm in length o <u>triple lumen devices</u> ▪ 1.2 mm ID and 275 mm in length ▪ 1.8 mm ID and 310 mm in length or ▪ 2.8 mm ID and 317 mm in length	The Vis-U-All Low Temperature Tyvek Sterilization Pouches are sterilization containment pouches for use by health care providers to enclose medical devices to be sterilized in the AMSCO V-PRO1 Low Temperature Sterilization System. The pouches maintain the sterility of the enclosed medical device during normal handling and storage until the pouch is opened and the medical device is removed for use.	Proposed Indications for Use include new sterilization cycles. Data demonstating safety and efficacy of the pouches in these cycles are presented in this submission.
Device Features	▪ Chevron end of pouches for ease of opening ▪ Chemical process indicator for EO	▪ Chevron end of pouches for ease of opening ▪ Chemical process indicator for EO	Same

7. Description of Safety and Substantial Equivalence

The device models are identical to the cleared predicate K090371.

Testing of the Vis-U-All Low Temperature Sterilization Pouch/Tubing as summarized in the table below demonstrated that the proposed pouch is qualified for use in the V-PRO 60 Sterilizer and is as safe, as effective, and performs the same as the predicate device.

Test		Acceptance Criteria	Conclusion
Effective Sterilant Penetration		Worst case test article shall be reproducibly sterilized under worst case ½ cycle conditions.	PASS
Pouch Integrity: Physical and Microbial Barrier Properties	Tensile Strength	Pouch material tensile strength will show no statistical difference between processed and unprocessed samples.	PASS
	Whole Package Integrity (Burst)	Pouch burst strength will show no statistical difference between processed and unprocessed pouches.	PASS
	Seal Strength	Pouch seal strength will show no statistical difference between processed and unprocessed pouches.	PASS
	Microbial Retention	Tyvek microbial retention will show no statistical difference between processed and unprocessed pouches.	PASS
Maintenance of Package Integrity		Packaged instruments shall remain sterile through event related and real time studies.	PASS
Aeration: Hydrogen Peroxide Residuals		Hydrogen peroxide residuals on the pouch will be reduced to acceptable levels for dermal contact.	PASS
Cytotoxicity		Pouch materials shall be non-cytotoxic following worst case exposure in a V-PRO 60 Sterilizer.	PASS

8. Conclusion

The Vis-U-All Low Temperature Sterilization Pouches/Tubing have been validated to meet the established performance criteria. The results of the verification studies demonstrate that the Vis-U-All Low Temperature Sterilization Pouch/Tubing performs as intended and the proposed device is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 22, 2014

Steris Corporation
Mr. Anthony Piotrkowski
Manager, Regulatory Affairs
5960 Heisley Rd
Mentor, OH 44060

Re: K140487
Trade/Device Name: Vis-U-All Low Temperature Sterilization Pouch/Tubing
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: June 20, 2014
Received: June 23, 2014

Dear Mr. Piotrkowski:

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,

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Clinical Deputy Director
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Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K140487

Device Name: **Vis-U-All Low Temperature Sterilization Pouch/Tubing**

Indications For Use:

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Table 4-1 Vis-U-All Low Temperature Pouch/Tubing Models and Sizes

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	14" x 100'	872141

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)

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000540490, cn=Sreekanth Gutala -S
Date: 2014.07.19 22:58:40 -04'00'