DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-000

July 22, 2016

STERIS Corporation
Mr. Anthony Piotrkowski
Sr. Manager, Regulatory Affairs
5960 Heisley Road
Mentor, OH 44060

Re: K160908
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 22, 2016
Received: June 23, 2016

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,

for 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

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160908

Device Name
Vis-U-All Low Temperature Sterilization Pouches/Tubing

Indications for Use *(Describe)*

The Vis-U-All Low Temperature Sterilization Pouches/Tubing are sterilization containment pouches for use by health care providers to enclose:

- medical devices in a single or double pouch configuration
- trays* containing medical devices in a single or double pouch configuration
- small items requiring surface sterilization in a single pouch configuration within a tray*

to be sterilized in the Lumen, Non Lumen and Flexible Cycles of the V-PRO Low Temperature Sterilization Systems. The pouches maintain the sterility of the enclosed devices until used.

When used to enclose medical devices, the pouches are intended to contain the devices in such a manner as to leave a minimum of one inch between the devices and seal on all sides. When used to enclose a tray, the tray must fit loosely within the pouch.

Vis-U-All Pouch/Tubing Claims with V-PRO Sterilization Systems

Intended Sterilization Cycles	**Intended Pouch Load when Medical Devices are:** • **Directly Pouched or** • **Placed Inside of a Tray* and the Tray* Pouched**
V-PRO 60 Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ 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
V-PRO 60 Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
V-PRO 60 Flexible Cycle	One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length
V-PRO 1, 1 Plus & maX Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 527 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

V-PRO 1 Plus & maX Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors.

V-PRO maX Flexible Cycle	Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load.
	The flexible endoscopes may contain either:
	• a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
	• or two lumens with:
	  • one lumen that is ≥ 1 mm ID and ≤ 990 mm in length
	  • and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
	Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.

*Trays must be legally marketed for use in the V-PRO Low Temperature Sterilization Systems and contain a vent surface area to tray volume ratio ≥ 0.135 in^{-1} with the maximum number of instrument organizers installed.

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.

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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STERIS®

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

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Submission Date: July 22, 2016

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).

2. Predicate Device

Vis-U-All Low Temperature Sterilization Pouch/Tubing (K140487)

Reference Device - Vis-U-All Low Temperature Sterilization Pouch/Tubing (K092745)

3. Description of Device

The proposed Vis-U-All Low Temperature Sterilization Pouch/Tubing is identical to the predicate and is a Tyvek/plastic film sterilization containment pouch designed for devices to be sterilized by the health care provider in V-PRO Low Temperature Sterilization Systems. As is the predicate, 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 add claims for: use in the V-PRO maX Flexible cycle; pouching of sterilization trays and for sterilization of pouched items within a sterilization tray.

4. Intended Use/ Indications for Use

The Vis-U-All Low Temperature Sterilization Pouches/Tubing are sterilization containment pouches for use by health care providers to enclose:

- medical devices in a single or double pouch configuration
- trays* containing medical devices in a single or double pouch configuration
- small items requiring surface sterilization in a single pouch configuration within a tray*

to be sterilized in the Lumen, Non Lumen and Flexible Cycles of the V-PRO Low Temperature Sterilization Systems. The pouches maintain the sterility of the enclosed devices until used.

When used to enclose medical devices, the pouches are intended to contain the devices in such a manner as to leave a minimum of one inch between the devices and seal on all sides. When used to enclose a tray, the tray must fit loosely within the pouch.

Vis-U-All Pouch/Tubing Claims with V-PRO Sterilization Systems

Intended Sterilization Cycles	**Intended Pouch Load when Medical Devices are:** • **Directly Pouched or** • **Placed Inside of a Tray* and the Tray* Pouched**
V-PRO 60 Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ 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
V-PRO 60 Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
V-PRO 60 Flexible Cycle	One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length
V-PRO 1, 1 Plus & maX Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 527 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
V-PRO 1 Plus & maX Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel diffusion-restricted spaces such as the hinged portion of forceps and scissors.
V-PRO maX Flexible Cycle	Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain either: • a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • or two lumens with: • one lumen that is ≥ 1 mm ID and ≤ 990 mm in length • and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.

*Trays must be legally marketed for use in the V-PRO Low Temperature Sterilization Systems and contain a vent surface area to tray volume ratio ≥ 0.135 in^{-1} with the maximum number of instrument organizers installed.

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. Description of Safety and Substantial Equivalence

The device models are identical to the cleared predicate K140487.

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
Package Integrity: Event Related Package Integrity Pouching a Qualified Tray	• No visual damage to pouch material (no holes or tears). • Seals remain intact.	PASS

7. 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 Pouches/Tubing are sterilization containment pouches for use by health care providers to enclose: • medical devices **in a single or double pouch configuration** • **trays* containing medical devices in a single or double pouch configuration** • **small items requiring surface sterilization in a single pouch configuration within a tray*** **to be sterilized in the Lumen, Non Lumen and Flexible Cycles of the V-PRO Low Temperature Sterilization Systems**. The pouches maintain the sterility of the enclosed devices until used.	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 maintain the sterility of the enclosed devices until used.	Similar (bolded text illustrates differences). Data is presented in this submission to support substantial equivalent use of the pouches in the additional cycles and load configurations.
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
Maintenance of Sterility	1 year	1 year	Same

8. Conclusion

In conclusion, the subject device the Vis-U-All Low Temperature Sterilization Pouches/Tubing is substantially equivalent to predicate device K140487 the Vis-U-All Low Temperature Sterilization Pouches/Tubing. Based on the intended use, technological characteristics, and performance data, the subject The Vis-U-All Low Temperature Sterilization Pouches/Tubing is substantially equivalent and is as safe and as effective as the legally marketed predicate device.