February 9, 2018

STERIS Corporation
Bill Brodbeck, Ph.D.
Director, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K172749
Trade/Device Name: Vis-U-All Low Temperature Sterilization Pouches/Tubing
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: January 9, 2018
Received: January 10, 2018

Dear Dr. Brodbeck:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172749

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, Flexible and Fast Non Lumen Cycles of the V-PRO Low Temperature Sterilization Systems. The pouches are intended to 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.
V-PRO maX 2 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 titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
V-PRO maX 2 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 maX 2 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.

V-PRO maX 2 Fast Non Lumen	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.

* 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.

FOR FDA USE ONLY

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

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STERIS®

510(k) Summary
for K172749
Vis-U-All Low Temperature Sterilization Pouches/Tubing

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060

Contact: Bill Brodbeck, Ph.D.
Director, Regulatory Affairs
Telephone: (440) 392-7690
Fax No: (440) 357-9198
E-mail: William_Brodbeck@steris.com

Date of Preparation: January 9, 2018

1. Device Name

Trade Name:	Vis-U-All Low Temperature Sterilization Pouches/Tubing
Device Classification:	Class II
Common/Usual Name:	Sterilization pouch
Classification Name:	Sterilization wrap
Classification Number:	21 CFR 880.6850
Product Code:	FRG

2. Predicate Device

Vis-U-All Low Temperature Sterilization Pouches/Tubing (K160908)

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

3. Description of Device

The proposed Vis-U-All Low Temperature Sterilization Pouches/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 device, the proposed device is available as a self seal pouch, a heat seal pouch, or heat seal tubing.

The purpose of K172749 is to add claims for:

- use in the V-PRO maX 2 Fast Non Lumen Cycle
- the sterilization of titanium mated surfaces (diffusion-restricted spaces) in the V-PRO 1 Plus, maX, and maX 2 Sterilizers Non Lumen Cycle
- addition of the V-PRO maX 2 Sterilizer to the indications for use in the Lumen, Non Lumen and Flexible Cycles of the V-PRO 1, 1 Plus and maX Sterilizers (the V-PRO maX 2 Sterilizer Lumen, Non Lumen, and Flexible Cycles are identical, with the exception of the condition phase of the Lumen Cycle, to the previously cleared cycles listed in **Table 2-1)**.

Table 2-1: V-PRO Cycles Provided in the Large Size (136 L Chamber) V-PRO Sterilizers

Cycle	Most Recent Premarket Notification Clearance		V-PRO 1	V-PRO 1 Plus	V-PRO maX	V-PRO maX 2
Lumen Cycle	K131120		X	X	X	X
Non Lumen Cycle	K160433		*	X	X	X
Flexible Cycle	K102330				X	X
Fast Non Lumen Cycle	Concurrent Submission					X

* Shaded cell indicates that the V-PRO Sterilizer does not include the identified cycle.

NOTE: V-PRO Sterilizer cycles are pre-set and thus the name of the cycle describes the cycle conditions.

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, Flexible and Fast Non Lumen Cycles of the V-PRO Low Temperature Sterilization Systems. The pouches are intended to 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: o single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 410 mm in length

Intended Sterilization Cycles	**Intended Pouch Load when Medical Devices are:** • **Directly Pouched or** • **Placed Inside of a Tray* and the Tray* Pouched**
	o 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: o 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: o single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 527 mm in length o 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

Intended Sterilization Cycles	**Intended Pouch Load when Medical Devices are:** • **Directly Pouched or** • **Placed Inside of a Tray* and the Tray* Pouched**
	Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.
V-PRO maX 2 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: o single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 527 mm in length o 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 titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
V-PROmaX 2 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 maX 2 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.
V-PRO maX 2 Fast Non Lumen	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless

Intended Sterilization Cycles	Intended Pouch Load when Medical Devices are: • **Directly Pouched or** • **Placed Inside of a Tray* and the Tray* Pouched**
	steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and 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)
Heat Seal Pouch	3 x 7
	4 x 9
	4 x 12
	4 x 22
	6 x 10
	8 x 12
	10 x 15
	12 x 18
Self Seal Pouch	3 x 7
	4 x 9
	4 x 12
	4 x 22
	6 x 10
	8 x 12
	10 x 15
	12 x 18
Tubing	3" x 100'
	4" x 100'
	6" x 100'
	9" x 100'
	14" x 100'

6. Description of Safety and Substantial Equivalence

Testing of the Vis-U-All Low Temperature Sterilization Pouches/Tubing as summarized in the table below demonstrated that the proposed pouch is qualified for use in the V-PRO maX 2 Fast Non Lumen Cycle and for sterilization of titanium mated surfaces (diffusion-restricted spaces) in the V-PRO 1 Plus, maX, and maX 2 Sterilizers Non Lumen Cycle and is as safe, as effective, and performs the same as the predicate device.

Test		Acceptance Criteria	Conclusion
Effective Sterilant Penetration into Pouches (including pouched trays and, if applicable, pouches placed within a tray):	V-PRO maX 2 Sterilizer Fast Non Lumen Cycle	Worst case test article shall be reproducibly sterilized under worst case abbreviated ½ cycle conditions for Fast Non Lumen Cycle.	PASS
		Diffusion-restricted spaces (composed of stainless steel and titanium, as well as contact points between medical devices and tray accessories) shall be reproducibly sterilized under worst case abbreviated ½ cycle conditions for Fast Non Lumen Cycle.	PASS
	V-PRO 1 Plus, maX, and maX 2 Sterilizer Non Lumen Cycle, diffusion restricted titanium claims	Diffusion-restricted spaces (titanium) shall be reproducibly sterilized under worst case ½ cycle conditions for the Non Lumen Cycle.	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 in Fast Non Lumen Cycle with 3 minute aeration.	PASS
Cytotoxicity		Pouch materials shall be non-cytotoxic following worst case exposure in a V-PRO Sterilizer for Fast Non Lumen Cycle with 3 minute aeration.	PASS

7. Comparison of Technological Characteristics

Characteristic	Proposed K172749	Predicate K160908	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, Flexible and Fast Non Lumen Cycles of the V-PRO Low Temperature Sterilization Systems. The pouches maintain the sterility of the enclosed devices until used. <u>V-PRO 1 Plus, maX, & maX 2 Non Lumen Cycle</u> - 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.	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. <u>V-PRO 1 Plus & maX Non Lumen Cycle</u> - 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.	Similar

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

The conclusions drawn from the nonclinical tests demonstrate that the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device K160908.