March 25, 2019

STERIS Corporation
Jennifer Nalepka
Senior Regulatory Affairs Specialist
5960 Heisley Rd
Mentor, Ohio 44060

Re: K183401
Trade/Device Name: Vis-U-All Low Temperature Sterilization Pouch/Tubing
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization wrap
Regulatory Class: Class II
Product Code: FRG
Dated: December 6, 2018
Received: December 7, 2018

Dear Jennifer Nalepka:

This letter corrects our substantially equivalent letter of March 1, 2019.

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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,

Clarence W. Murray Iii III -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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183401

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

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

and to be sterilized in the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen and Fast Cycles of the V-PRO® Low Temperature Sterilization Systems
- Default Cycle of the STERRAD 100S Sterilizer
- Standard and Advanced Cycles of the STERRAD NX and NX with ALLClear Technology Sterilizers
- Express, Standard, Flex Scope, and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers

*STERRAD and ALLClear are trademarks of Advanced Sterilization Products

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.

Intended Sterilization Cycles and Intended Pouch Loads when Medical Devices are:

- Directly pouched
- Placed inside of a tray and the tray pouched

V-PRO 60 & s2 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 internal diameter (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 & s2 Non Lumen Cycle

Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

V-PRO 60 & s2 Flexible Cycle

Load 1: 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

Load 2: Non-lumened devices including non-lumened rigid, semi-rigid, and flexible endoscopes and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors. Medical devices, including rigid and semi-rigid endoscopes, with the following dimensions:

- ≥ 2 mm ID and ≤ 400 mm in length
- ≥ 0.76 mm ID and ≤ 233 mm in length
- ≥ 1.0 mm ID and ≤ 254 mm in length

V-PRO s2 Fast Cycle

- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes, and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors.
- Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
  - Single or dual channeled devices with stainless steel lumens that are ≥ 0.77 mm ID and ≤ 410 mm in length
  - Triple channeled devices with stainless steel lumens that are either:
    - ≥ 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, 1 Plus, maX & 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 internal diameter (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 & 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 & 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 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.

STERRAD 100S Default Cycle

- Metal and non-metal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Metal and non metal lumened instruments with:
  - ≥ 6 mm ID and ≤ 310 mm in length
- Medical devices with a single stainless steel lumen with:
  - ≥ 1 mm ID and ≤ 125 mm in length
  - ≥ 2 mm ID and ≤ 250 mm in length
  - ≥ 3 mm ID and ≤ 400 mm in length

STERRAD NX and NX with ALLClear Technology Standard Cycle

- Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices with a single stainless steel lumen with:
  - ≥ 1 mm ID and ≤ 150 mm in length
  - ≥ 2 mm ID and ≤ 400 mm in length

STERRAD NX and NX with ALLClear Technology Advanced Cycle

- Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical Devices, including most flexible endoscopes, with:
  - a single stainless steel lumen with:
    - ≥ 1 mm ID and ≤ 500 mm in length
  - single channel polyethylene and Teflon (polytetrafluoroethylene):
    - ≥ 1 mm ID and ≤ 850 mm in length

STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle

- Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices with a single stainless steel lumen with:
  - ≥ 0.7 mm ID and ≤ 500 mm in length

STERRAD 100NX and 100NX with ALLClear Technology Flex Cycle

- Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical Devices, including most flexible endoscopes, with:
  - Single channel polyethylene and Teflon (polytetrafluoroethylene)
    - ≥ 1 mm ID and ≤ 850 mm in length

STERRAD 100NX and 100NX with ALLClear Technology Express Cycle

Metal and nonmetal medical devices surfaces and instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

STERRAD 100NX and 100NX with ALLClear Technology Duo Cycle

- Medical devices including:
  - most flexible endoscopes with a single channel of polyethylene and Teflon (polytetrafluoroethylene) with ≥ 1 mm ID and ≤ 875 mm in length
  - accessory devices that are normally connected to a flexible endoscope during use
  - flexible endoscopes without lumens

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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STERIS®

K183401 510(k) Summary
for
Vis-U-All Low Temperature Sterilization Pouches/Tubing

Sponsor Facility

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Submission Date: December 6, 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, K172749

Reference Device: Vis-U-All Low Temperature Sterilization Pouch/Tubing K183297

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. Available sizes and configurations are shown in **Table 1.**

Table 1. Sizes and Configurations of Vis-U-All Low Temperature Sterilization Pouches/Tubing

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
	8 x 21
	8 x 27
	9 x 27
	11 x 22
	12 x 27
Tubing	3" x 100'
	4" x 100'
	6" x 100'
	9" x 100'
	14" x 100'

The purpose of this submission is to allow for use of the products in the following sterilizer cycles:

- STERRAD® 100S Sterilizer Default Cycle
- STERRAD NX® with and without ALLClear™ Technology Sterilizer Standard and Advanced Cycles
- STERRAD 100NX® with and without ALLClear Technology Sterilizer Standard, Flex Scope, Express and Duo Cycles

4. 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

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

and to be sterilized in the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen and Fast Cycles of the V-PRO® Low Temperature Sterilization Systems
- Default Cycle of the STERRAD® 100S Sterilizer
- Standard and Advanced Cycles of the STERRAD NX and NX with ALLClear™ Technology Sterilizers
- Express, Standard, Flex Scope, and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers

*STERRAD and ALLClear are trademarks of Advanced Sterilization Products

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.

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 & s2 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 internal diameter (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 & s2 Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
V-PRO 60 & s2 Flexible Cycle	Load 1: 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 Load 2: Non-lumened devices including non-lumened rigid, semi-rigid, and flexible endoscopes and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors. Medical devices, including rigid and semi-rigid endoscopes, with the following dimensions: ○ ≥ 2.0 mm ID and ≤ 400 mm in length ○ ≥ 1.0 mm ID and ≤ 254 mm in length ○ ≥0.76 mm ID and ≤ 233 mm in length
V-PRO s2 Fast 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 channeled devices: ○ ≥ 0.77 mm ID and ≤ 410 mm in length • triple channeled 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

Intended Sterilization Cycles	**Intended Pouch Load when Medical Devices are:** • **Directly Pouched or** • **Placed Inside of a Tray and the Tray Pouched**
V-PRO 1, 1 Plus, maX & 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 & 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 & 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 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.
STERRAD 100S (Default Cycle)	Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Metal and nonmetal lumened instruments with: • ≥ 6 mm ID and ≤ 310 mm in length Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 125 mm in length • ≥ 2 mm ID and ≤ 250 mm in length • ≥ 3 mm ID and ≤ 400 mm in length
STERRAD NX and NX with ALLClear Technology Standard Cycle	Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 150 mm in length • ≥ 2 mm ID and ≤ 400 mm in length
STERRAD NX and NX with ALLClear Technology Advanced Cycle	Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical Devices, including most flexible endoscopes, with: • a single stainless steel lumen with: o ≥ 1 mm ID and ≤ 500 mm in length • Single channel polyethylene and Teflon (polytetrafluoroethylene) o ≥ 1 mm ID and ≤ 850 mm in length
STERRAD 100NX and	Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Intended Sterilization Cycles	Intended Pouch Load when Medical Devices are: • Directly Pouched or • Placed Inside of a Tray and the Tray Pouched
100NX with ALLClear Technology Standard Cycle	Medical devices with a single stainless steel lumen with: • ≥ 0.7 mm ID and ≤ 500 mm in length
STERRAD 100NX and 100NX with ALLClear Technology Flex Scope Cycle	Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical Devices, including most flexible endoscopes, with: • Single channel polyethylene and Teflon (polytetrafluoroethylene) o ≥ 1 mm ID and ≤ 850 mm in length
STERRAD 100NX and 100NX with ALLClear Technology Express Cycle	Metal and nonmetal medical devices (surfaces sterilization only) and instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
STERRAD 100NX and 100NX with ALLClear Technology Duo Cycle	Medical devices including: • most flexible endoscopes with a single channel of polyethylene and Teflon (polytetrafluoroethylene) with ≥ 1 mm ID and ≤ 875 mm in length • accessory devices that are normally connected to a flexible endoscope during use • flexible endoscopes without lumens

5. Technological Characteristics

The proposed and predicate devices are single use sterilization pouches for use in V-PRO Sterilizers. **Table 3** summarizes the difference between the proposed device and predicate device cleared under K172749.

Table 3. Technical Characteristic Comparison Table

Characteristic	K183401	Predicate K172749
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 NOTE: Trays must be legally	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

	marketed for use in the V-PRO Low Temperature or STERRAD Sterilization Systems and contain a vent surface area to tray volume ratio ≥ 0.135 in^{-1} with the maximum number of instrument organizers installed. and to be sterilized in the: • Lumen, Non Lumen, Flexible, Fast Non Lumen and Fast Cycles of the V-PRO® Low Temperature Sterilization Systems • Default Cycle of the STERRAD® 100S Sterilizer • Standard and Advanced Cycles of the STERRAD NX and NX with ALLClear™ Technology Sterilizers • Express, Standard, Flex Scope, and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers *STERRAD and ALLClear are trademarks of Advanced Sterilization Products 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. <u>V-PRO 60 & s2 Lumen Cycle</u> • 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	Lumen 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. <u>V-PRO 60 Lumen Cycle</u> • 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 internal diameter (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 & s2 Non Lumen Cycle Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors. V-PRO 60 & s2 Flexible Cycle Load 1: 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 Load 2: Non-lumened devices including non-lumened rigid, semi-rigid, and flexible endoscopes and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors. Medical devices, including rigid and semi-rigid endoscopes, with the following dimensions: • ≥ 2 mm ID and ≤ 400 mm in length • ≥ 0.76 mm ID and ≤ 233 mm in length • ≥1.0 mm ID and ≤ 254 mm in length	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 s2 Fast Cycle
	• Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes, and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors.
	• Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
	  • Single or dual channeled devices with stainless steel lumens that are ≥ 0.77 mm ID and ≤ 410 mm in length
	  • Triple channeled devices with stainless steel lumens that are either:
	  ≥ 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, 1 Plus, maX & 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, 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, 1 Plus, maX & maX2 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 and 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 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.
	
	STERRAD 100S Default Cycle
	Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
		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

	Metal and nonmetal lumened instruments with: • ≥ 6 mm ID and ≤ 310 mm in length Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 125 mm in length • ≥ 2 mm ID and ≤ 250 mm in length • ≥ 3 mm ID and ≤ 400 mm in length STERRAD NX and NX with ALLClear Technology Standard Cycle Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 150 mm in length • ≥ 2 mm ID and ≤ 400 mm in length STERRAD NX and NX with ALLClear Technology Advanced Cycle Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical Devices, including most flexible endoscopes, with: • a single stainless steel lumen with: o ≥ 1 mm ID and ≤ 500 mm in length • Single channel polyethylene and Teflon (polytetrafluoroethylene) o ≥1 mm ID and ≤ 850 mm in length	▪ ≥ 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 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 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.

	STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with a single stainless steel lumen with: • ≥ 0.7 mm ID and ≤ 500 mm in length STERRAD 100NX and 100NX with ALLClear Technology Flex Scope Cycle Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical Devices, including most flexible endoscopes, with: • Single channel polyethylene and Teflon (polytetrafluoroethylene) o ≥ 1 mm ID and ≤ 850 mm in length STERRAD 100NX and 100NX with ALLClear Technology Express Cycle Metal and nonmetal medical devices (surfaces sterilization only) and instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. STERRAD 100NX and 100NX with ALLClear Technology Duo Cycle Medical devices including: • most flexible endoscopes with a single channel of polyethylene and Teflon (polytetrafluoroethylene) with ≥ 1 mm ID and ≤ 875 mm in length • accessory devices that are normally connected to a flexible endoscope during use	* 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.

	• flexible endoscopes without lumens	
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
Maintenance of Sterility	1 year	1 year
Materials of Construction	Tyvek and plastic	Tyvek and plastic
Types	Self Seal, Heat Seal, Tubing	Self Seal, Heat Seal, Tubing
Chemical Indicator	Ethylene Oxide Process Chemical Indicator Printed on both sides of Tyvek	Ethylene Oxide Process Chemical Indicator Printed on both sides of Tyvek

6. Summary of Non-Clinical Testing

Table 4 summarizes the testing of the Vis-U-All Low Temperature Sterilization Pouches/Tubing to demonstrate that the proposed pouch is qualified for use in STERRAD 100S Sterilizer Default Cycle, STERRAD NX and NX with ALLClear Technology Sterilizer Standard and Advanced Cycles, and the STERRAD 100NX with and without ALLClear Technology Sterilizer Standard, Flex Scope, Express and Duo Cycles.

Table 4. Performance Test Summary

Test		Acceptance Criteria	Conclusion
Effective Sterilant Penetration into Pouches (including pouched trays and, if applicable, pouches placed within a tray):		Worst case test articles shall be reproducibly sterilized under worst case ½ cycle conditions for the: • STERRAD 100S Default Cycle • STERRAD NX Standard Cycle • STERRAD NX Advanced Cycle • STERRAD 100NX Standard Cycle • STERRAD 100NX Flex Scope Cycle • STERRAD 100NX Express Cycle • STERRAD 100NX Duo 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

Test	Acceptance Criteria	Conclusion
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	PASS

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective, and performs as well as or better than the legally marketed predicate device (K172749), Class II (21 CFR 880.6850), product code FRG.