September 9, 2022

Steris
Anthony Piotrkowski
Director Regulatory Affairs
5960 Heisey Road
Mentor, Ohio 44060

Re: K222440
    Trade/Device Name: Vis-U-All Low Temperature Sterilization Pouches / Tubing, PRO-LITE
                       Sterilization Trays
    Regulation Number: 21 CFR 880.6850
    Regulation Name: Sterilization Wrap
    Regulatory Class: Class II
    Product Code: FRG, KCT
    Dated: August 11, 2022
    Received: August 12, 2022

Dear Anthony 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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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, PhD
Assistant Director
DHT4B: Division of Infection Control
    and Plastic Surgery Devices
OHT4: Office of Surgical
    and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023

See PRA Statement below.

510(k) Number *(if known)*
 K222440

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.

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
• Non-lumened devices 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 internal diameter (ID) and ≤ 410 mm in length
≥ 1.8 mm ID x ≤ 542 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 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 configurations:
  ≥ 0.76 mm ID and ≤ 233 mm in length
  ≥ 1.0 mm ID and ≤ 254 mm in length
  ≥ 1.8 mm ID and ≤ 542 mm in length

V-PRO s2 Fast Cycle
• Non-lumened devices including non-lumened rigid and semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
• 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
    ≥ 1.8 mm ID x ≤ 542 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
• Non-lumened devices 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 or triple channeled stainless steel lumens that are:
≥ 0.77 mm ID and ≤ 527 mm in length
≥ 0.8 mm ID and ≤ 542 mm in length
≥ 0.48 mm ID and ≤ 100 mm in length
• Medical devices with Dead end lumens that are ≥ 1.3 mm ID and ≤ 73 mm in length
• Devices with rigid non-metallic lumens (such as those used in endoscope sheaths, take-apart forceps and trocars) that are:
≥ 3 mm ID and ≤ 298 mm in length
≥ 4 mm ID and ≤ 424 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 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 or dual channel lumen that is > 1 mm ID and < 1050 mm in length
Load 2:
• 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
• Single, dual or triple channel stainless steel lumen that is ≥ 0.48 mm ID and ≤ 100 mm in length.

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 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:
≥ 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 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)
≥ 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

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2023

See PRA Statement below.

510(k) Number *(if known)*
 K222440

Device Name
 PRO-LITE Sterilization Tray

Indications for Use *(Describe)*
The PRO-LITE Sterilization Trays are used to contain medical devices for sterilization in the following Cycles:
• 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
• Standard, Flex Scope, Express and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers

*STERRAD and ALLClear are trademarks of Advanced Sterilization Products

Prior to placing in the Sterilizer, the trays must either be:
• wrapped with a legally marketed sterilization wrap for use in the Sterilizers listed above
or
• placed inside a legally marketed pouch for enclosing trays in the Sterilizers listed above.

The PRO-LITE Sterilization Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap or pouch in order to maintain sterility of the enclosed medical instruments.

Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052

V-PRO 60 and s2 Lumen Cycle:
• Non-lumened devices 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 channeled devices with stainless steel lumens that are:
≥ 0.77 mm ID and ≤ 410 mm in length
≥ 1.8 mm ID x ≤ 542 mm in length
o Triple channeled devices with stainless steel lumens that are:
≥ 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 and 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 and 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 configurations:

≥ 0.76 mm ID and ≤ 233 mm in length
≥ 1.0 mm ID and ≤ 254 mm in length
≥ 1.8 mm ID and ≤ 542 mm in length

Intended Sterilization Cycle and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049

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 and scissors.
• Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
o Single or dual channeled devices with stainless steel lumens
≥ 0.77 mm ID and ≤ 410 mm in length
≥ 1.8 mm ID and ≤ 542 mm in length
o 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
≥ 2.8 mm ID and ≤ 317 mm in length

Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052, VP0053

V-PRO 1, 1 Plus, maX, and maX 2 Lumen Cycle:
• Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Medical devices, including single, dual or triple channeled stainless steel lumens that are:
≥ 0.77 mm ID and ≤ 527 mm in length
≥ 0.8 mm ID and ≤ 542 mm in length
≥ 0.48 mm ID and ≤ 100 mm in length
• Medical devices with dead end stainless steel lumens that are ≥ 1.3 mm ID and ≤ 73 mm in length
• Devices with rigid non-metallic lumens (such as those used in endoscope sheaths, take-apart forceps and trocars) that are:
≥ 3 mm ID and ≤ 298 mm in length
≥ 4 mm ID and ≤ 424 mm in length

V-PRO 1 Plus, maX, and maX 2 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 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 or dual lumen that is ≥ 1 mm ID and ≤ 1050 mm in length.
Load 2:
• 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
• Single, dual or triple channel stainless steel lumens that are ≥ 0.48 mm ID and ≤ 100 mm in length

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 diffusion-restricted spaces such as the hinged portion of forceps and scissors.

Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049,

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

Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0048, VP0049

STERRAD NX and NX with ALLClear Technology Standard Cycle:
Metal and non-metal 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

STERRAND NX and NX with ALLClear Technology Advanced Cycle:
Metal and non-metal 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:
 o a single stainless steel lumen with:
   ≥ 1 mm ID and ≤ 500 mm in length
 o single channel polyethylene and Teflon (polytetrafluoroethylene)
   ≥ 1mm ID and ≤ 850 mm in length

Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0048, VP0049, VP0051, VP0052, VP0053

STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle:
Metal and nonmetal medical devices including instruments with 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)
≥ 1mm ID and ≤ 850 mm in length

STERRAD 100NX and 100NX with ALLClear Technology Express Cycle:
Metal and nonmetal 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.

STERIS®

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

Sponsor Facility

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Anthony Piotrkowski
                Director, Regulatory Affairs

Telephone: (440) 392-7437
Fax No: (440) 357-9198
e-mail: tony_piotrkowski@steris.com

Submission Date: September 7, 2022

Premarket Notification Number: K222440

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, K183401

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 or STERRAD 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 *	Type	Size*	Type	Size*
Heat Seal Pouch	3 x 7	Self Seal Pouch	3 x 7	Tubing	3" x 100'
	4 x 9		4 x 9		4" x 100'
	4 x 12		4 x 12		6" x 100'
	4 x 22		4 x 22		9" x 100'
	6 x 10		6 x 10		14" x 100'
	8 x 12		8 x 12		
	10 x 15		10 x 15		
	12 x 18		12 x 18		
			8 x 21		
			8 x 27		
			9 x 27		
			11 x 22		
			12 x 27		

      Sizes are in inches unless specified otherwise

The purpose of this submission is to qualify use of the Vis-U-All Low Temperature Sterilization Pouches and Tubing for extended claims in the V-PRO 60, s2, maX and maX 2 Sterilizer Cycles.

4.   Intended Use/ Indications for Use

The Vis-U-All Low Temperature Sterilization Pouches/Tubing Intended use remains the same. The indications for use are being modified to expand lumen claims. A detailed comparison of the cleared and proposed indications for use are provided in **Table 2**.

5.   Comparison of the Modified Device to the Predicate

The proposed and predicate devices are single use sterilization pouches for use in V-PRO Sterilizers. **Table 2** summarizes the difference between the proposed device and predicate device cleared under K183401.

Table 2. Technical Comparison to the Predicate.

Feature	Modified Vis-U-All Low Temperature Sterilization Pouch **(proposed) K222440**	Vis-U-All Low Temperature Sterilization Pouch (K183401)	Comparison
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* 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. 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	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. 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	Identical except for: • Clarification of lumen claims for V-PRO lumen cycles • Clarification of endoscope claims for V-PRO flexible cycles • Removal of "stainless steel or titanium" from V-PRO Non Lumen cycles.

Feature	Modified Vis-U-All Low Temperature Sterilization Pouch **(proposed) K222440**	Vis-U-All Low Temperature Sterilization Pouch (K183401)	Comparison

	*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
	
	<u>V- PRO 60 & s2 Lumen Cycle</u>
	• Non-lumened devices 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 internal diameter (ID) and ≤ 410 mm in length
	    ▪ ≥ 1.8 mm ID x ≤ 542 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
		*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
		
		<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 semi-rigid endoscopes, with the following configurations:
		  o single or dual lumen devices
		    ▪ ≥ 0.77 mm internal diameter (ID) and ≤ 410 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	

Feature	Modified Vis-U-All Low Temperature Sterilization Pouch **(proposed) K222440**	Vis-U-All Low Temperature Sterilization Pouch (K183401)	Comparison

	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 $\geq$ 1 mm ID and $\leq$ 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 configurations:
	• $\geq$ 0.76 mm ID and $\leq$ 233 mm in length
	• $\geq$ 1.0 mm ID and $\leq$ 254 mm in length
	• $\geq$ 1.8 mm ID and $\leq$ 542 mm in length
	
	V-PRO s2 Fast Cycle
	• Non-lumened devices including non-lumened rigid and semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	• Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
	  o single or dual lumen devices
	    ▪ $\geq$ 0.77 mm ID and $\leq$ 410 mm in length
	    ▪ $\geq$ 1.8 mm ID x $\leq$ 542 mm in length
	• Triple channeled devices with stainless steel lumens that are either:
		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 $\geq$ 1 mm ID and $\leq$ 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:
		• $\geq$ 2 mm ID and $\leq$ 400 mm in length
		• $\geq$ 0.76 mm ID and $\leq$ 233 mm in length
		• $\geq$ 1.0 mm ID and $\leq$ 254 mm in length
		
		V-PRO s2 Fast Cycle
		• Non-lumened devices including non-lumened rigid and semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and 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 $\geq$ 0.77 mm ID and $\leq$ 410 mm in length
		
		• Triple channeled devices with stainless steel lumens that are either:	

Feature	Modified Vis-U-All Low Temperature Sterilization Pouch **(proposed) K222440**	Vis-U-All Low Temperature Sterilization Pouch (K183401)	Comparison
	▪ ≥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 • Non-lumened devices 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 or triple channeled stainless steel lumens that are: ▪ ≥ 0.77 mm ID and ≤ 527 mm in length ▪ ≥ 0.8 mm ID and ≤ 542 mm in length ▪ ≥ 0.48 mm ID and ≤ 100 mm in length • Medical devices with Dead end lumens that are ≥ 1.3 mm ID and ≤ 73 mm in length • Devices with rigid non-metallic lumens (such as those used in endoscope sheaths, take-apart forceps and trocars) that are: ▪ ≥ 3 mm ID and ≤ 298 mm in length ▪ ≥ 4 mm ID and ≤ 424 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 diffusion-restricted spaces such as the hinged portion of forceps and scissors. V-PRO maX and maX 2 Flexible Cycle	▪ ≥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: o single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 410 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, 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	

Feature	Modified Vis-U-All Low Temperature Sterilization Pouch **(proposed) K222440**	Vis-U-All Low Temperature Sterilization Pouch (K183401)	Comparison
	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 or dual channel lumen that is ≥ 1 mm ID and ≤ 1050 mm in length Load 2: - 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 - Single, dual or triple channel stainless steel lumen that is ≥ 0.48 mm ID and ≤ 100 mm in length. 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 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.	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.	

Feature	Modified Vis-U-All Low Temperature Sterilization Pouch **(proposed) K222440**	Vis-U-All Low Temperature Sterilization Pouch (K183401)	Comparison

	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 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-
		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 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	

Feature	Modified Vis-U-All Low Temperature Sterilization Pouch **(proposed) K222440**	Vis-U-All Low Temperature Sterilization Pouch (K183401)	Comparison
	restricted spaces, such as the hinged portion of forceps and scissors. <u>STERRAD 100NX and 100NX with ALLClear Technology Duo Cycle</u> 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	instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. <u>STERRAD 100NX and 100NX with ALLClear Technology Duo Cycle</u> 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	
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	Identical
Maintenance of Sterility	1 year	1 year	Identical
Materials of Construction	Tyvek and plastic	Tyvek and plastic	Identical
Types	Self Seal, Heat Seal, Tubing	Self Seal, Heat Seal, Tubing	Identical

6. <u>Summary of Performance Testing</u>

Table 3 summarizes the testing of the Vis-U-All Low Temperature Sterilization Pouches/Tubing to demonstrate that the proposed pouch is qualified for use in V-PRO Low temperature Sterilization Systems.

Table 3. Performance Test Summary

Test	Result	Conclusion
½ Cycle Verification of Mated Surfaces	Sterile efficacy was demonstrated for mated surfaces under worst case conditions in the V-PRO Sterilizer cycles.	PASS
½ Cycle Efficacy	The standard injection weight resulted in all sterile results within the validation load used to qualify each sterilizer cycle.	PASS
Simulated Use Test	Simulated use testing verified the ability of the sterilizer cycles to sterilize medical devices under worst-case processing conditions.	PASS
In Use Test	The in use investigation demonstrated the ability of the V-PRO Sterilizer cycles to sterilize patient-soiled, clinically-cleaned, medical instruments.	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 (K183401), Class II (21 CFR 880.6850), product code FRG.

510(k) Summary
For
PRO-LITE^{TM} Sterilization Tray

Sponsor Facility

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060
Phone: (440) 354-2600
Fax No: (440) 357-9198

Contact: Anthony Piotrkowski
                 Director, Regulatory Affairs

Telephone: (440) 392-7437
Fax No: (440) 357-9198
e-mail: tony_piotrkowski@steris.com

Submission Date: September 7, 2022

Premarket Notification Number: K222440

7.   **Device Name**
     Trade Name: PRO-LITE Sterilization Tray
     Common/usual Name: Sterilization Trays, cassettes and other accessories
     Classification Name: Sterilization Wrap
     Classification   21 CFR 880.6850
     Class   II
     Product Code   KCT, FRG

8.   **Predicate Device**
     PRO-LITE Sterilization Tray, K183402

9.   **Description of Device**
     The PRO-LITE Sterilization Trays contain medical devices for sterilization in the
     V-PRO Low Temperature Sterilization Systems and STERRAD Sterilizers. The
     trays are available in various sizes, outlined in **Table 4,** to accommodate the loads
     to be processed. The proposed trays are identical in design to the predicate
     Sterilization Tray (K183402) and are composed of a base and a lid. The lid includes
     clamping mechanisms designed to secure the lid onto the base. There are numerous
     holes in the base and lid for sterilant penetration. The tray is categorized as a
     cassette and requires complete enclosure in a legally-marketed sterilization wrap or
     pouch to maintain sterility of the enclosed devices. Both the base and the lid for the
     proposed tray are made of a mineral-filled polypropylene material.

Table 4. External Dimensions of Tray Line

Model	Description (in)	Model	Description (in)	Model	Description (in)
VP0045	13 x 4.5 x 2.25	VP0048	13 x 7.75 x 2.25	VP0051	12 x 11.75 x 4
VP0046	19 x 4.5 x 2.25	VP0049	19 x 7.75 x 2.25	VP0052	25 x 11.75 x 4
VP0047	25 x 4.5 x 2.25	VP0050	27 x 7.75 x 4	VP0053	25 x 14 x 5

     Optional instrument organizers are provided as accessories to the trays and allow
     stabilization of various cylindrical medical devices during processing. **Table 5** lists
     the organizer sizes. The organizers are either "blank" and are used to partition the
     tray or have a device holding portion into which the devices are inserted. At the
     organizer base is a flapped groove that is used to position the organizer within a
     PRO-LITE Sterilization Tray.

Table 5. Instrument Organizer Model Numbers

Model	Description	Model	Description
VP0054	Blank, Tall	VP0055	Blank, Short
VP0063	3 mm - 7mm, Tall	VP0067	3 mm - 7 mm, Short
VP0064	7 mm - 11mm, Tall	VP0068	7 mm -11 mm, Short
VP0065	11 mm - 15 mm, Tall	VP0069	11 mm - 15 mm, Short
VP0066	15 mm - 19mm, Tall	VP0070	15 mm – 19 mm, Short

STERIS Corporation ▪ 5960 Heisley Road ▪ Mentor, OH 44060-1834 USA ▪ 440-354-2600

Optional sterilization mats are provided as accessories to the trays. The mats, which are used to cushion and stabilize devices placed into the trays, are available in sizes as shown in **Table 6** to fit the nine PRO-LITE Sterilization Trays. The mats are a diamond grid design with "fingers" that extend from each corner of the diamond and at the midpoint of each diamond side. The fingers cushion and stabilize instruments, helping to prevent the instruments from freely moving in the tray during packaging, sterilization and storage. The cushioning and stabilization qualities help protect delicate instruments placed into the trays.

Table 6. Silicone Mat Model Numbers

Model	Description (in)	Model	Description (in)	Model	Description (in)
VP0071	13 x 4.5	VP0074	13 x 7.75	VP0077	12 x 11.75
VP0072	19 x 4.5	VP0075	19 x 7.75	VP0078	25 x 11.75
VP0073	25 x 4.5	VP0076	27 x 7.75	VP0079	25 x 14

The purpose of this submission is to expand claims for the use of these tray models in the following sterilizer cycles:

- V-PRO 1, 1 Plus, maX and maX 2 Lumen Cycle
- V-PRO 1 Plus, maX and maX 2 Non Lumen Cycle
- V-PRO maX and maX 2 Flexible Cycle
- V-PRO maX 2 Fast Non Lumen Cycle
- V-PRO 60 and s2 Lumen, Non Lumen and Flexible Cycles
- V-PRO s2 Fast Cycle

10. Intended Use/ Indications for Use
The tray indications for use are included in Table 7 which compares the proposed device to the predicate.

Instrument organizers are optional accessories intended to stabilize cylindrical medical instruments within the PRO-LITE Sterilization Trays.

Model	Description	Model	Description
VP0054	Blank, Tall	VP0055	Blank, Short
VP0063	3 mm - 7 mm, Tall	VP0067	3 mm - 7 mm, Short
VP0064	7 mm - 11 mm, Tall	VP0068	7 mm - 11 mm, Short
VP0065	11 mm - 15 mm, Tall	VP0069	11 mm - 15 mm, Short
VP0066	15 mm - 19 mm, Tall	VP0070	15 mm - 19 mm, Short

Sterilization mats are optional accessories intended to cushion and stabilize instruments within the PRO-LITE Sterilization Trays.

Model	Description (in)	Model	Description (in)	Model	Description (in)
VP0071	13 x 4.5	VP0074	13 x 7.75	VP0077	12 x 11.75
VP0072	19 x 4.5	VP0075	19 x 7.75	VP0078	25 x 11.75
VP0073	25 x 4.5	VP0076	27 x 7.75	VP0079	25 x 14

11. **Summary of Technical Characteristics**

The proposed PRO-LITE sterilization trays, sterilization mats and instrument organizers are identical in composition to the claimed predicate device. The technical characteristics are summarized below in **Table 7**.

Table 7. Summary of Tray Physical Description and Technological Properties

Feature	PRO-LITE Sterilization Tray (proposed) K222440	PRO-LITE Sterilization Tray (K183402)	Comparison
Intended Use / Indications for Use	The PRO-LITE Sterilization Trays are used to contain medical devices for sterilization in the following Cycles: • 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 • Standard, Flex Scope, Express and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers *STERRAD and ALLClear are trademarks of Advanced Sterilization Products Prior to placing in the Sterilizer, the trays must either be: • wrapped with a legally marketed sterilization wrap for use in the Sterilizers listed above or • placed inside a legally marketed pouch for enclosing trays in the Sterilizers listed above. The PRO-LITE Sterilization Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap or pouch in order to maintain sterility of the enclosed medical instruments.	The PRO-LITE Sterilization Trays are used to contain medical devices for sterilization in the following Cycles: • 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 • Standard, Flex Scope, Express and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers *STERRAD and ALLClear are trademarks of Advanced Sterilization Products Prior to placing in the Sterilizer, the trays must either be: • wrapped with a legally marketed sterilization wrap for use in the Sterilizers listed above or • placed inside a legally marketed pouch for enclosing trays in the sterilizers listed above The PRO-LITE Sterilization Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap or pouch in order to maintain sterility of the enclosed medical instruments.	Identical except for: • Clarification of lumen claims for V-PRO lumen cycles • Clarification of endoscope claims for V-PRO flexible cycles Removal of "stainless steel or titanium" from V-PRO Non Lumen cycles.

Feature	PRO-LITE Sterilization Tray (proposed) K222440	PRO-LITE Sterilization Tray (K183402)	Comparison

	Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052
	
	V-PRO 60 and s2 Lumen Cycle:
	• Non-lumened devices 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 channeled devices with stainless steel lumens that are:
	    ▪ ≥ 0.77 mm ID and ≤ 410 mm in length
	    ▪ ≥ 1.8 mm ID x ≤ 542 mm in length
	  o Triple channeled devices with stainless steel lumens that are:
	    ▪ ≥ 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 and 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 and 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:
		Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052
		
		V-PRO 60 and 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:
		  o Single or dual lumen devices
		    ▪ ≥ 0.77 mm ID and ≤ 410 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 60 and 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 and 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:	

Feature	PRO-LITE Sterilization Tray (proposed) K222440	PRO-LITE Sterilization Tray (K183402)	Comparison

	• 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 configurations:
	• ≥ 0.76 mm ID and ≤ 233 mm in length
	• ≥ 1.0 mm ID and ≤ 254 mm in length
	• ≥ 1.8 mm ID and ≤ 542 mm in length
	
	Intended Sterilization Cycle and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049
	
	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 and 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
	  ▪ ≥ 0.77 mm ID and ≤ 410 mm in length
	  ▪ ≥ 1.8 mm ID and ≤ 542 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
	  ▪ ≥ 2.8 mm ID and ≤ 317 mm in length
		• 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 configurations:
		• ≥ 2.0 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 spaces such as the hinged portion of forceps and 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
		  ▪ ≥ 2.8 mm ID and ≤ 317 mm in length	

Feature	PRO-LITE Sterilization Tray (proposed) K222440	PRO-LITE Sterilization Tray (K183402)	Comparison
	Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052, VP0053 V-PRO 1, 1 Plus, maX, and maX 2 Lumen Cycle: • Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices, including single, dual or triple channeled stainless steel lumens that are: ○ ≥ 0.77 mm ID and ≤ 527 mm in length ○ ≥ 0.8 mm ID and ≤ 542 mm in length ○ ≥ 0.48 mm ID and ≤ 100 mm in length • Medical devices with dead end stainless steel lumens that are ≥ 1.3 mm ID and ≤ 73 mm in length • Devices with rigid non-metallic lumens (such as those used in endoscope sheaths, take-apart forceps and trocars) that are: ○ ≥ 3 mm ID and ≤ 298 mm in length ○ ≥ 4 mm ID and ≤ 424 mm in length V-PRO 1 Plus, maX, and maX 2 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 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.	Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0050, VP0051, VP0052, VP0053 V-PRO 1, 1 Plus, maX, and maX 2 Lumen Cycle: • Instruments with diffusion-restricted spaces such as the hinged portions 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 ▪ ≥ 2.8 mm ID and ≤ 317 mm in length V-PRO 1 Plus, maX, and 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, 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.	

Feature	PRO-LITE Sterilization Tray (proposed) K222440	PRO-LITE Sterilization Tray (K183402)	Comparison

	The flexible endoscopes may contain either a single or dual lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
	<u>Load 2:</u>
	• 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
	• Single, dual or triple channel stainless steel lumens that are ≥ 0.48 mm ID and ≤ 100 mm in length
	
	<u>V-PRO maX 2 Fast Non Lumen Cycle:</u>
	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.
	
	Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052
	
	<u>STERRAD 100S Default Cycle:</u>
	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
	
	Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0048, VP0049
	
	<u>STERRAD NX and NX with ALLClear Technology Standard Cycle:</u>
		The flexible endoscopes may contain either:
		• a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
		• or two lumens with:
		  o one lumen that is ≥ 1 mm ID and ≤ 990 mm in length
		  o and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
		<u>Load 2:</u> Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.
		
		<u>V-PRO maX 2 Fast 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
		
		Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052
		
		<u>STERRAD 100S Default Cycle:</u>
		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
		
		Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0048, VP0049	

Feature	PRO-LITE Sterilization Tray (proposed) K222440	PRO-LITE Sterilization Tray (K183402)	Comparison

	Metal and non-metal 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
	
	STERRAND NX and NX with ALLClear Technology Advanced Cycle:
	Metal and non-metal 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:
	o a single stainless steel lumen with:
	  o ≥ 1 mm ID and ≤ 500 mm in length
	o single channel polyethylene and Teflon (polytetrafluoroethylene)
	  o ≥ 1mm ID and ≤ 850 mm in length
	
	Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0048, VP0049, VP0051, VP0052, VP0053
	
	STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle:
	Metal and nonmetal medical devices including instruments with 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:
		STERRAD NX and NX with ALLClear Technology Standard Cycle:
		Metal and non-metal 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
		
		STERRAND NX and NX with ALLClear Technology Advanced Cycle:
		Metal and non-metal 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:
		o a single stainless steel lumen with:
		  o ≥ 1 mm ID and ≤ 500 mm in length
		o single channel polyethylene and Teflon (polytetrafluoroethylene)
		  o ≥ 1mm ID and ≤ 850 mm in length
		
		Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0048, VP0049, VP0051, VP0052, VP0053
		
		STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle:
		Metal and nonmetal medical devices including instruments with 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.	

Feature	PRO-LITE Sterilization Tray (proposed) K222440	PRO-LITE Sterilization Tray (K183402)	Comparison
	• Single channel polyethylene and Teflon (polytetrafluoroethylene) ○ ≥ 1mm ID and ≤ 850 mm in length STERRAD 100NX and 100NX with ALLClear Technology Express Cycle: Metal and nonmetal 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	Medical devices, including most flexible endoscopes, with: • Single channel polyethylene and Teflon (polytetrafluoroethylene) ○ ≥ 1mm ID and ≤ 850 mm in length STERRAD 100NX and 100NX with ALLClear Technology Express Cycle: Metal and nonmetal 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	
Vent to Volume Ratio	All trays are the same: 0.135 in^{-1}	All trays are the same: 0.135 in^{-1}	Identical
Tray Composition	Mineral-filled polypropylene, stainless steel	Mineral-filled polypropylene, stainless steel	Identical
Instrument Organizer Composition	Medical Grade Silicone, UPS grade VI	Medical Grade Silicone, UPS grade VI	Identical
Mat Composition	Medical Grade Silicone, UPS grade VI	Medical Grade Silicone, UPS grade VI	Identical

12. **Summary of Non-clinical Tests**
     Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 8** below.

Table 8. Performance Test Summary

Test	Result	Conclusion
½ Cycle Verification of Mated Surfaces	Sterile efficacy was demonstrated for mated surfaces under worst case conditions in the V-PRO Sterilizer cycles.	PASS
½ Cycle Efficacy	The standard injection weight resulted in all sterile results within the validation load used to qualify each sterilizer cycle.	PASS

Test	Result	Conclusion
Simulated Use Test	Simulated use testing verified the ability of the sterilizer cycles to sterilize medical devices under worst-case processing conditions.	PASS
In Use Test	The in use investigation demonstrated the ability of the V-PRO Sterilizer cycles to sterilize patient-soiled, clinically-cleaned, medical instruments.	PASS

7. **Conclusion**

Based on the intended us, 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 (K183402), Class II (21 CFR 880.6850), product code KCT.