August 7, 2023

STERIS Corporation
Jennifer Nalepka
Manager, Regulatory Affairs
5960 Heisley Road
Mentor, Ohio 44060

Re: K231500
Trade/Device Name: Vis-U-All Low Temperature Sterilization Pouches
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: May 22, 2023
Received: May 24, 2023

Dear Jennifer Nalepka:

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,

Christopher K. Dugard -S

for Clarence W. Murray, III, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231500

Device Name
Vis-U-All Low Temperature Sterilization Pouches

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

*3-D printed items should not be double pouched.

to be sterilized in the:
• Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast and Specialty 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

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.

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.

V-PRO 60 & s2 Lumen Cycle
• Non-lumened instruments and 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
≥ 1.8 mm ID x ≤ 542 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 instruments 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, 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 lumen devices
≥ 0.77 mm ID and ≤ 410 mm in length
≥ 1.8 mm ID and ≤ 542 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 & maX 2 Lumen Cycle
• Non-lumened instruments and 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 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
• Instruments 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 instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

V-PRO maX and maX 2 Flexible Cycle

• Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two load configurations:
○ Load 1: Two flexible endoscopes with single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length with a light cord (if not integral to endoscope) and mat with no additional load

○ Load 2: One flexible endoscope with single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length with a light cord (if not integral to endoscope), endoscope accessories, mat, and additional instruments that may include non-lumened or lumened medical devices with the following configurations:
○ 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 instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

V-PRO maX 2 Specialty Cycle:
Patient-specific surgical guides (e.g. osteotomy, shoulder, hip, knee, spine) or anatomical models fabricated via additive manufacturing (3D printing) processes and intended for single-use during operative procedures.*
or
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.**
* The validation studies were conducted using a validation load consisting of pouched guide(s)/model(s) (with or without tray) for a total weight of 5 lbs (2.3 kg) 3D printed material.
** The validation studies were conducted using a validation load consisting of one pouched instrument tray or one pouched instrument tray or one pouch with guide(s)/model(s) (with or without tray) for a total weight of 11 lbs (5 kg).

Material	Manufacturer	Specialty Cycle	Lumens
Surgical Guide Resin	Formlabs	F	≥3 mm ID x ≤30 mm L
BioMed Amber Resin	Formlabs	F	≥3 mm ID x ≤30 mm L
Dental LT Clear V2 Resin	Formlabs	D	≥3 mm ID x ≤30 mm L
BioMed Clear Resin	Formlabs	D	≥3 mm ID x ≤30 mm L
Biocompatible Clear MED610	Stratasys	E	≥3 mm ID x ≤20 mm L
Biocompatible Opaque MED615RGD	Stratasys	E	≥3 mm ID x ≤20 mm L
VeroGlaze™ MED620	Stratasys	E	≥3 mm ID x ≤20 mm L

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

*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.

Ethylene Oxide Sterilization
The Vis-U-All Low Temperature Sterilization Pouch has been qualified by STERIS as suitable for use by health care providers to enclose and seal other medical devices to be sterilized by ethylene oxide (ETO). The Vis-U-All Low Temperature Sterilization Pouch for ethylene oxide is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use.

The following are the validated test conditions:
• 1 hour exposure, at 130(±5) °F, * >30% RH using 100% ETO (750-790 mg/L)
• 4.5 hour exposure at 100(±5) °F, * >30% RH using 100% ETO (750-790 mg/L)
*±5 °F is used during sterilization phase following an equilibrium period of 10% of exposure time.

The ethylene oxide process indicator is intended to be used by health care providers with the Vis- U-All Low Temperature

Sterilization Pouches to distinguish between processed and unprocessed units.

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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510(k) Summary
for K231500
Vis-U-All Low Temperature Sterilization Pouches/Tubing

Sponsor Facility

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

Contact: Jennifer Nalepka
Manager, Regulatory Affairs

Telephone: (440) 392-7458
e-mail: jennifer_nalepka@steris.com

Submission Date: July 28, 2023

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, K222400 (Vaporized Hydrogen Peroxide claims)

Vis-U-All Low Temperature Sterilization Pouches/Tubing, K092745 (Ethylene Oxide claims)

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 5-1.**

Table 5-1. 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

Type	Size (inches unless specified)
	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 qualify use of the Vis-U-All Low Temperature Sterilization Pouches and Tubing for extended claims in the V-PRO maX 2 Specialty Cycle. No changes have been made to the device for this claim other than labeling.

4. Intended Use/ Indications for Use

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

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

*3-D printed items should not be double-pouched.

to be sterilized in the:

- Lumen, Non Lumen, Flexible, Fast Non Lumen, Fast and Specialty 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.

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.

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.

V-PRO 60 & s2 Lumen Cycle

- Non-lumened instruments and 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
    - ≥ 1.8 mm ID x ≤ 542 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 instruments 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:
    - ≥ 1.8 mm ID and ≤ 542 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

- 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 lumen devices
    - ≥ 0.77 mm ID and ≤ 410 mm in length
    - ≥ 1.8 mm ID and ≤ 542 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 & maX 2 Lumen Cycle

- Non-lumened instruments and 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 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
- Instruments 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. Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors

V-PRO maX and maX 2 Flexible Cycle

- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two load configurations:
  - Load 1: Two flexible endoscopes with single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length with a light cord (if not integral to endoscope) and mat with no additional load
  - Load 2: One flexible endoscope with single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length with a light cord (if not integral to endoscope), endoscope accessories, mat, and additional instruments that may include non-lumened or lumened medical devices with the following configurations:
    - 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.

V-PRO maX 2 Specialty 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. Patient-specific surgical guides (e.g. osteotomy, shoulder, hip, knee, spine) or anatomical models fabricated via additive manufacturing (3D printing) processes and intended for single-use during operative procedures

* The validation studies were conducted using a validation load consisting of pouched guide(s)/model(s)) (with or without tray) for a total weight of 5 lbs (2.3 kg) 3D printed material.
** The validation studies were conducted using a validation load consisting of one pouched instrument tray or one pouched instrument tray or one pouch with) (with or without tray) for a total weight of 5 lbs (2.3 kg) 3D printed material.

Material	Manufacturer	Specialty Cycle	Lumens
Surgical Guide Resin	Formlabs	F	≥3 mm ID x ≤30 mm L
BioMed Amber Resin	Formlabs	F	≥3 mm ID x ≤30 mm L
Dental LT Clear V2 Resin	Formlabs	D	≥3 mm ID x ≤30 mm L
BioMed Clear Resin	Formlabs	D	≥3 mm ID x ≤30 mm L
Biocompatible Clear MED610	Stratasys	E	≥3 mm ID x ≤20 mm L
Biocompatible Opaque MED615RGD	Stratasys	E	≥3 mm ID x ≤20 mm L
VeroGlaze™ MED620	Stratasys	E	≥3 mm ID x ≤20 mm L

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

*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.

Ethylene Oxide Sterilization

The Vis-U-All Low Temperature Sterilization Pouch has been qualified by STERIS as suitable for use by health care providers to enclose and seal other medical devices to be sterilized by ethylene oxide (ETO). The Vis-U-All Low Temperature Sterilization Pouch for ethylene oxide is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use.

The following are the validated test conditions:

- 1 hour exposure, at 130(±5) °F, * >30% RH using 100% ETO (750-790 mg/L)
- 4.5 hour exposure at 100(±5) °F, * >30% RH using 100% ETO (750-790 mg/L)

*±5 °F is used during sterilization phase following an equilibrium period of 10% of exposure time.

The ethylene oxide process indicator is intended to be used by health care providers with the Vis-U-All Low Temperature Sterilization Pouches to distinguish between processed and unprocessed units.

5. Description of Safety and Substantial Equivalence

The proposed and predicate devices are single use sterilization pouches for use in V-PRO Sterilizers. **Tables 5-2** and **5-3** summarizes the difference between the proposed device and predicate device cleared under K222440 and K092745.

Table 5-2. Technical Comparison to the K222440 Predicate Device (Vaporized Hydrogen Peroxide claims)

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K222440)
Intended Use /	The Vis-U-All Low Temperature Sterilization Pouches/Tubing are sterilization containment pouches for use by	The Vis-U-All Low Temperature Sterilization Pouches/Tubing are sterilization containment pouches for use by

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K222440)
Indications for Use	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 *3-D printed items should not be double-pouched 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** l00S 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 l00NX and l00NX with ALLClear Technology Sterilizers **STERRAD and ALLClear are trademarks of Advanced Sterilization Products 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. 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-	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 l00S 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 l00NX and l00NX 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-

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K222440)
	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 ≥ 1.8 mm ID x ≤ 542 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 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	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 ≥ 1.8 mm ID x ≤ 542 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 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

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K222440)
	≥ 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 1.8mm ID and 310mm 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	≥ 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 1.8mm ID and 310mm 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

<table>
<tr><th>Feature</th><th>Vis-U-All Low Temperature Sterilization Pouch (proposed, K231500)</th><th>Vis-U-All Low Temperature Sterilization Pouch (K222440)</th></tr>
<tr><td></td><td>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.

V-PRO maX 2 Specialty Cycle:

Patient-specific surgical guides (e.g. osteotomy, shoulder, hip, knee, spine) or anatomical models fabricated via additive manufacturing (3D printing) processes and intended for single-use during operative procedures.*
or
Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.**
* The validation studies were conducted using a validation load consisting of pouched guide(s)/model(s) (with or without tray) for a total weight of 5 lbs (2.3 kg) 3D printed material.
** The validation studies were conducted using a validation load consisting of one pouched instrument tray or one pouched instrument tray or one pouch with guide(s)/model(s) (with or without tray) for a total weight of 11 lbs (5 kg).

<table>
<tr><th>Material</th><th>Manufacturer</th><th>Specialty Cycle</th><th>Lumens</th></tr>
<tr><td>Surgical Guide Resin</td><td>Formlabs</td><td>F</td><td>≥3 mm ID x ≤30 mm L</td></tr>
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<tr><td>Biocompatible Clear MED610</td><td>Stratasys</td><td>E</td><td>≥3 mm ID x ≤20 mm L</td></tr>
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<tr><td>VeroGlaze™ MED620</td><td>Stratasys</td><td>E</td><td>≥3 mm ID x ≤20 mm L</td></tr>
</table></td><td>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.</td></tr>
</table>

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K222440)
	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 l00NX and l00NX 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 l00NX and l00NX with ALLClear Technology Flex Scope Cycle** Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion	**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 l00NX and l00NX 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 l00NX and l00NX with ALLClear Technology Flex Scope Cycle** Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K222440)
	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 l00NX and l00NX 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 l00NX and l00NX 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 **Ethylene Oxide Sterilization** The Vis-U-All Low Temperature Sterilization Pouch has been qualified by STERIS as suitable for use by health care providers to enclose and seal other medical devices to be sterilized by ethylene oxide (ETO). The Vis-U-All Low Temperature Sterilization Pouch for ethylene oxide is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use. The following are the validated test conditions: • 1 hour exposure, at 130(±5) °F, * >30% RH using 100% ETO (750-790 mg/L) • 4.5 hour exposure at 100(±5) °F, * >30% RH using 100% ETO (750-790 mg/L) *±5 °F is used during sterilization phase following an equilibrium period of 10% of exposure time.	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 l00NX and l00NX 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 l00NX and l00NX 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

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K222440)
	The ethylene oxide process indicator is intended to be used by health care providers with the Vis- U-All Low Temperature Sterilization Pouches to distinguish between processed and unprocessed units.	
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

Table 5-3. Technical Comparison to the K092745 Predicate Device (Ethylene Oxide Claims)

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K092745)
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 *3-D printed items should not be double-pouched 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** l00S 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 l00NX and l00NX with ALLClear Technology Sterilizers **STERRAD and ALLClear are trademarks of Advanced Sterilization Products NOTE: Trays must be legally marketed for use in the V PRO Low Temperature or	The Vis-U-All Low Temperature Sterilization Pouch has been qualified by STERIS as suitable for use by health care providers to enclose and seal other medical devices to be sterilized by ethylene oxide (ETO). The Vis-U-All Low Temperature Sterilization Pouch for ethylene oxide is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use. The following are the validated test conditions: • 1 hour exposure, at 130(±5) °F, * >30% RH using 100% ETO (750-790 mg/L) • 4.5 hour exposure at 100(±5) °F, * >30% RH using 100% ETO (750-790 mg/L) *±5 °F is used during sterilization phase following an equilibrium period of 10% of exposure time. The ethylene oxide process indicator is intended to be used by health care providers with the Vis- U-All Low Temperature Sterilization Pouches to distinguish between processed and unprocessed units.

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K092745)
	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. 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: 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 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	

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K092745)
	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 1.8mm ID and 310mm 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	

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K092745)
	≥ 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. **V-PRO maX 2 Specialty Cycle:** Patient-specific surgical guides (e.g. osteotomy, shoulder, hip, knee, spine) or anatomical models fabricated via additive manufacturing (3D printing) processes and intended for single-use during operative procedures.* or Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.** * The validation studies were conducted using a validation load consisting of pouched	

<table>
<tr><th>Feature</th><th>Vis-U-All Low Temperature Sterilization Pouch (proposed, K231500)</th><th>Vis-U-All Low Temperature Sterilization Pouch (K092745)</th></tr>
<tr><td></td><td>guide(s)/model(s) (with or without tray) for a total weight of 5 lbs (2.3 kg) 3D printed material.
** The validation studies were conducted using a validation load consisting of one pouched instrument tray or one pouched instrument tray or one pouch with guide(s)/model(s) (with or without tray) for a total weight of 11 lbs (5 kg).

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<tr><th>Material</th><th>Manufacturer</th><th>Specialty Cycle</th><th>Lumens</th></tr>
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<tr><td>VeroGlaze™ MED620</td><td>Stratasys</td><td>E</td><td>≥3 mm ID x ≤20 mm L</td></tr>
</table>

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-</td><td></td></tr>
</table>

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K092745)
	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 l00NX and l00NX 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 l00NX and l00NX 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 l00NX and l00NX 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 l00NX and l00NX 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 **Ethylene Oxide Sterilization** The Vis-U-All Low Temperature Sterilization Pouch has been qualified by	

Feature	Vis-U-All Low Temperature Sterilization Pouch **(proposed, K231500)**	Vis-U-All Low Temperature Sterilization Pouch (K092745)
	STERIS as suitable for use by health care providers to enclose and seal other medical devices to be sterilized by ethylene oxide (ETO). The Vis-U-All Low Temperature Sterilization Pouch for ethylene oxide is designed to maintain sterility of properly processed medical devices during normal handling and storage until the pouch is opened and the medical device is removed for use. The following are the validated test conditions: • 1 hour exposure, at 130(±5) °F, * >30% RH using 100% ETO (750-790 mg/L) • 4.5 hour exposure at 100(±5) °F, * >30% RH using 100% ETO (750-790 mg/L) *±5 °F is used during sterilization phase following an equilibrium period of 10% of exposure time. The ethylene oxide process indicator is intended to be used by health care providers with the Vis- U-All Low Temperature Sterilization Pouches to distinguish between processed and unprocessed units.	
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

Table 5-4 summarizes the testing of the Vis-U-All Low Temperature Sterilization Pouches/Tubing to demonstrate that the proposed pouch is qualified for use in V-PRO Low temperature Sterilization Systems and is as safe, as effective, and performs the same as the predicate device.

Table 5-4. 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 136L V-PRO Sterilizer Specialty Cycle	PASS

8. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs at least as well as the legally marketed predicate devices (K222440, K092745), Class II (21 CFR 880.6850), product code FRG.