

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 <a href="https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm">https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm</a> 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 <a href="https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products">https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products</a>); 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 <u>https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems</u>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance</u>) and CDRH Learn (<u>https://www.fda.gov/training-and-continuing-education/cdrh-learn</u>). 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 (<u>https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice</u>) for more information or contact DICE by email (<u>DICE@fda.hhs.gov</u>) 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

#### 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  $\ge 0.135$  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

 $\geq$  0.77 mm internal diameter (ID) and  $\leq$  410 mm in length

 $\geq$  1.8 mm ID x  $\leq$  542 mm in length

• triple lumen devices

 $\geq$ 1.2 mm ID and  $\leq$  275 mm in length

 $\geq 1.8 \text{ mm ID and} \leq 310 \text{ mm in length}$ 

- or
- $\geq$ 2.8 mm ID and  $\leq$  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:

 $\circ$  single or dual lumen device with lumens that are  $\geq 1 \text{ mm ID}$  and  $\leq 990 \text{ mm in length}$ 

•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:

 $\circ~\geq 0.76~mm$  ID and  $\leq 233~mm$  in length

 $\odot \geq 1.0 \text{ mm}$  ID and  $\leq 254 \text{ mm}$  in length

 $\circ \ge 1.8 \text{ mm ID}$  and  $\le 542 \text{ mm in length}$ 

#### 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

 $\circ$  Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

• Single or dual lumen devices

 $\geq 0.77 \text{ mm}$  ID and  $\leq 410 \text{ mm}$  in length

 $\geq$  1.8 mm ID and  $\leq$  542 mm in length

• triple lumen devices

 $\geq$ 1.2 mm ID and  $\leq$  275 mm in length

 $\geq$ 1.8 mm ID and  $\leq$  310 mm in length

or

 $\geq$ 2.8 mm ID and  $\leq$  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:

 $\geq$  0.77 mm ID and  $\leq$  527 mm in length

 $\geq$  0.8 mm ID and  $\leq$  542 mm in length

 $\geq 0.48 \text{ mm}$  ID and  $\leq 100 \text{ mm}$  in length

• Medical devices with Dead end stainless steel lumens that are  $\geq$  1.3 mm ID and  $\leq$  73 mm in length

• Instruments with rigid non-metallic lumens (such as those used in endoscope sheaths, take-apart forceps and trocars) that are:

 $\geq$  3 mm ID and  $\leq$  298 mm in length

 $\geq 4 \text{ mm ID}$  and  $\leq 424 \text{ mm}$  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 FORM FDA 3881 (6/20) • 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:

 $\circ$  Load 1: Two flexible endoscopes with single or dual channel lumens that are  $\geq$  1 mm ID and  $\leq$  1050 mm in length with a light cord (if not integral to endoscope) and mat with no additional load

 $\circ$  Load 2: One flexible endoscope with single or dual channel lumens that are  $\geq 1 \text{ mm ID}$  and  $\leq 1050 \text{ mm}$  in length with a light cord (if not integral to endoscope), endoscope accessories, mat, and additional instruments that may include nonlumened or lumened medical devices with the following configurations:

Single, dual or triple channel stainless steel lumen that is  $\geq 0.48$  mm ID and  $\leq 100$  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	$\geq$ 3 mm ID x $\leq$ 30 mm L
BioMed Amber Resin	Formlabs	F	$\geq$ 3 mm ID x $\leq$ 30 mm L
Dental LT Clear V2 Resin	Formlabs	D	$\geq$ 3 mm ID x $\leq$ 30 mm L
BioMed Clear Resin	Formlabs	D	$\geq$ 3 mm ID x $\leq$ 30 mm L
Biocompatible Clear MED610	Stratasys	Е	$\geq$ 3 mm ID x $\leq$ 20 mm L
Biocompatible Opaque MED615RGD	Stratasys	E	$\geq$ 3 mm ID x $\leq$ 20 mm L
VeroGlaze <sup>TM</sup> MED620	Stratasys	E	$\geq$ 3 mm ID x $\leq$ 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:
- $\geq$  6 mm ID and < 310 mm in length
- Medical devices with a single stainless steel lumen with:
  - $\geq$  1 mm ID and  $\leq$  125 mm in length
  - $\geq$  2 mm ID and  $\leq$  250 mm in length
  - $\geq$  3 mm ID and  $\leq$  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:

 $\geq$  2 mm ID and  $\leq$  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:

 $\geq$  1 mm ID and < 500 mm in length

Single channel polyethylene and Teflon (polytetrafluoroethylene)

 $\geq$ 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:

 $\geq 0.7 \text{ mm}$  ID and  $\leq 500 \text{ mm}$  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)

 $\geq 1 \text{ mm ID}$  and  $\leq 850 \text{ mm}$  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:

 $\circ$  most flexible endoscopes with a single channel of polyethylene and Teflon (polytetrafluoroethylene) with  $\ge 1 \text{ mm ID}$  and  $\le 875 \text{ mm}$  in length

 $\circ$  accessory devices that are normally connected to a flexible endoscope during use

 $\circ$  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  $\geq 0.135$  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 TemperatureFORM FDA 3881 (6/20)Page 4 of 5

Ste	ril	izat	tion	Poucl	hes t	o di	istin	guis	h	between	processed	and	un	processed	units	;.
								0								

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 5960 Heisley Road 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

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

## 1. <u>Device Name</u>

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. <u>Predicate Device</u>

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. <u>Description of Device</u>

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**.

Туре	Size (inches unless specified)
	3 x 7
	4 x 9
	4 x 12
Heat Seel Dough	4 x 22
Heat Sear Fouch	6 x 10
	8 x 12
	10 x 15
	12 x 18
	3 x 7
	4 x 9
Self Seal Pouch	4 x 12
	4 x 22
	6 x 10

**Table 5-1.** Sizes and Configurations of Vis-U-All Low Temperature Sterilization

 Pouches/Tubing

Туре	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
	3" x 100'
	4" x 100'
Tubing	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. <u>Intended Use/ Indications for Use</u>

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  $\geq$  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:
- o <u>single or dual lumen devices</u>
  - $\geq 0.77$  mm internal diameter (ID) and  $\leq 410$  mm in length
  - $\geq 1.8 \text{ mm ID } x \leq 542 \text{ mm in length}$
- o triple lumen devices
  - $\geq 1.2 \text{ mm ID and} \leq 275 \text{ mm in length}$
  - $\geq 1.8 \text{ mm ID and} \leq 310 \text{ mm in length}$
  - $\geq 2.8 \text{ mm ID and} \leq 317 \text{ mm in length}$

#### 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:
  - o single or dual lumen device with lumens that are  $\geq 1 \text{ mm ID}$  and  $\leq 990 \text{ mm}$  in length
- <u>Load 2</u>: 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:
  - $\geq 1.8 \text{ mm ID and} \leq 542 \text{ mm in length}$
  - $\geq 1.0 \text{ mm ID and} \leq 254 \text{ mm in length}$
  - $\geq 0.76 \text{ mm ID and} \leq 233 \text{ mm in length}$

## 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:
- o <u>Single or dual lumen devices</u>
  - $\geq 0.77 \text{ mm ID and} \leq 410 \text{ mm in length}$
  - $\geq 1.8 \text{ mm ID and} \leq 542 \text{ mm in length}$
- o <u>triple lumen devices</u>
  - $\geq 1.2 \text{ mm ID and} \leq 275 \text{ mm in length}$
  - $\geq 1.8 \text{ mm ID and} \leq 310 \text{ mm in length}$

or

•  $\geq 2.8 \text{ mm ID and} \leq 317 \text{ mm in length}$ 

#### 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:
  - $\geq 0.77 \text{ mm ID and} \leq 527 \text{ mm in length}$
  - $\geq 0.8 \text{ mm ID and} \leq 542 \text{ mm in length}$
  - $\geq 0.48 \text{ mm ID and} \leq 100 \text{ mm in length}$
- Medical devices with Dead end stainless steel lumens that are  $\geq$  1.3 mm ID and  $\leq$  73 mm in length
- Instruments with rigid non-metallic lumens (such as those used in endoscope sheaths, take-apart forceps and trocars) that are:
  - $\geq$  3 mm ID and  $\leq$  298 mm in length
  - $\geq$  4 mm ID and  $\leq$  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  $\leq 1050$  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	$\geq$ 3 mm ID x $\leq$ 30 mm L
BioMed Amber Resin	Formlabs	F	$\geq$ 3 mm ID x $\leq$ 30 mm L
Dental LT Clear V2 Resin	Formlabs	D	$\geq$ 3 mm ID x $\leq$ 30 mm L
BioMed Clear Resin	Formlabs	D	$\geq$ 3 mm ID x $\leq$ 30 mm L
Biocompatible Clear MED610	Stratasys	Е	≥3 mm ID x ≤20 mm L
Biocompatible Opaque MED615RGD	Stratasys	Е	≥3 mm ID x ≤20 mm L
VeroGlaze <sup>™</sup> MED620	Stratasys	Е	≥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:
  - $\geq$  6 mm ID and  $\leq$  310 mm in length
- Medical devices with a single stainless steel lumen with:
  - $\geq 1 \text{ mm ID and} \leq 125 \text{ mm in length}$
  - $\geq 2 \text{ mm ID and} \leq 250 \text{ mm in length}$
  - $\geq$  3 mm ID and  $\leq$  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:
  - $\geq 1 \text{ mm ID and} \leq 150 \text{ mm in length}$
  - $\geq 2 \text{ mm ID and } \leq 400 \text{ mm in length}$

#### 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:
- <u>a single stainless steel lumen with:</u>
  - $\geq$  1 mm ID and  $\leq$  500 mm in length
- <u>Single channel polyethylene and Teflon (polytetrafluoroethylene)</u>
  - $\geq 1 \text{ mm ID and } \leq 850 \text{ mm in length}$

#### 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:
  - $\geq 0.7 \text{ mm ID and} \leq 500 \text{ mm in length}$

#### 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:
- o Single channel polyethylene and Teflon (polytetrafluoroethylene)
  - $\geq 1 \text{ mm ID and } \leq 850 \text{ mm in length}$

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
- o 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  $\geq 0.135$  in<sup>-1</sup> 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)

 $*\pm 5$  °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. <u>Description of Safety and Substantial Equivalence</u>

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 (VaporizedHydrogen Peroxide claims)

Footure	Vis-U-All Low Temperature Sterilization	Vis-U-All Low Temperature Sterilization
reature	Pouch (proposed, K231500)	Pouch (K222440)
Intended	The Vis-U-All Low Temperature	The Vis-U-All Low Temperature
	Sterilization Pouches/Tubing are	Sterilization Pouches/Tubing are
Use /	sterilization containment pouches for use by	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	<ul> <li>health care providers to enclose:</li> <li>medical devices in a single or double pouch configuration</li> <li>trays* containing medical devices in a single or double pouch configuration</li> <li>small items requiring surface sterilization in a single pouch configuration within a tray</li> <li>*3-D printed items should not be double-pouched</li> </ul>	<ul> <li>health care providers to enclose:</li> <li>medical devices in a single or double pouch configuration</li> <li>trays* containing medical devices in a single or double pouch configuration</li> <li>small items requiring surface sterilization in a single pouch configuration within a tray</li> </ul>
	<ul> <li>to be sterilized in the:</li> <li>Lumen , Non Lumen, Flexible , Fast Non Lumen and Fast Cycles of the V-PRO ® Low Temperature Sterilization Systems</li> <li>Default Cycle of the STERRAD** 100S Sterilizer</li> <li>Standard and Advanced Cycles of the STERRAD NX and NX with ALLClear** Technology Sterilizers</li> <li>Express, Standard, Flex Scope and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers</li> <li>**STERRAD and ALLClear are trademarks of Advanced Sterilization Products</li> <li>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.</li> </ul>	<ul> <li>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.</li> <li>to be sterilized in the:</li> <li>Lumen , Non Lumen , Flexible , Fast Non Lumen and Fast Cycles of the V-PRO ® Low Temperature Sterilization Systems</li> <li>Default Cycle of the STERRAD 100S Sterilizer</li> <li>Standard and Advanced Cycles of the STERRAD NX and NX with ALLClear Technology Sterilizers</li> <li>Express, Standard, Flex Scope and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers</li> <li>*STERRAD and ALLClear are trademarks of Advanced Sterilization Products</li> </ul>
	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.	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.
	<ul> <li>Intended Sterilization Cycles and Intended</li> <li>Pouch Loads when Medical Devices are:</li> <li>Directly pouched</li> <li>Placed inside of a tray and the tray pouched</li> </ul>	<ul> <li>Intended Sterilization Cycles and Intended Pouch Loads when Medical Devices are:</li> <li>Directly pouched</li> <li>Placed inside of a tray and the tray pouched</li> </ul>
	<ul> <li>V-PRO 60 &amp; s2 Lumen Cycle</li> <li>Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.</li> <li>Non-lumened devices including non-</li> </ul>	<ul> <li>V-PRO 60 &amp; s2 Lumen Cycle</li> <li>Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.</li> <li>Non-lumened devices including non-</li> </ul>

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 $\geq 0.77$ mm internal diameter (ID) and $\leq 410$ mm in length $\geq 1.8$ mm ID x $\leq 542$ mm in length triple lumen devices $\geq 1.2$ mm ID and $\leq 275$ mm in length $\geq 1.8$ mm ID and $\leq 310$ mm in length Or $\geq 2.8$ mm ID and $\leq 317$ 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 $\geq 0.77$ mm internal diameter (ID) and $\leq 410$ mm in length $\geq 1.8$ mm ID x $\leq 542$ mm in length triple lumen devices $\geq 1.2$ mm ID and $\leq 275$ mm in length $\geq 1.8$ mm ID and $\leq 310$ mm in length $\geq 1.8$ mm ID and $\leq 317$ mm in length Or $\geq 2.8$ mm ID and $\leq 317$ mm in length
	<b>V-PRO 60 &amp; s2 Non Lumen Cycle</b> 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.	<b>V-PRO 60 &amp; s2 Non Lumen Cycle</b> 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.
	<ul> <li>V-PRO 60 &amp; s2 Flexible Cycle</li> <li>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:</li> <li>single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length</li> <li>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:</li> <li>≥ 0.76 mm ID and ≤ 233 mm in length ≥ 1.0 mm ID and ≤ 542 mm in length</li> </ul>	<ul> <li>V-PRO 60 &amp; s2 Flexible Cycle</li> <li>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:</li> <li>single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length</li> <li>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:</li> <li>≥ 0.76 mm ID and ≤ 233 mm in length ≥ 1.0 mm ID and ≤ 542 mm in length</li> </ul>
	<ul> <li>V-PRO s2 Fast Cycle</li> <li>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.</li> <li>Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations: <ul> <li>o single or dual lumen devices</li> <li>&gt; 0.77 mm ID and &lt; 410 mm in length</li> </ul> </li> </ul>	<ul> <li>V-PRO s2 Fast Cycle</li> <li>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.</li> <li>Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations: <ul> <li>o single or dual lumen devices</li> <li>&gt; 0.77 mm ID and &lt; 410 mm in length</li> </ul> </li> </ul>

E (	Vis-U-All Low Temperature Sterilization	Vis-U-All Low Temperature Sterilization
Feature	Pouch (proposed, K231500)	Pouch (K222440)
	$\geq$ 1.8 mm ID x $\leq$ 542 mm in length	$\geq$ 1.8 mm ID x $\leq$ 542 mm in length
	• Triple channeled devices with stainless	• Triple channeled devices with stainless
	steel lumens that are either:	steel lumens that are either:
	$\geq$ 1.2 mm ID and $\leq$ 275 mm in length	$\geq 1.2 \text{ mm ID and} \leq 275 \text{ mm in length}$
	1.8mm ID and 310mm in length	1.8mm ID and 310mm in length
	$\bigcup_{n \to \infty} U_n = U_n = \frac{1}{2} (217 \text{ mm} \text{ is less oth})$	$\bigcup_{n \to \infty} U_n = \int d d d d d d d d d d d d d d d d d d$
	$\geq 2.8 \text{ mm ID and} \leq 317 \text{ mm in length}$	$\geq 2.8 \text{ mm ID and} \leq 317 \text{ mm in length}$
	V-PRO 1, 1 Plus, maX & maX 2	V-PRO 1, 1 Plus, maX & maX 2
	• Non-lumened devices with diffusion-	• Non-lumened devices with diffusion-
	restricted spaces such as the hinged	restricted spaces such as the hinged
	portion of forceps and scissors.	portion of forceps and scissors.
	• Non-lumened devices including non-	• Non-lumened devices including non-
	lumened rigid and semi-rigid	lumened rigid and semi-rigid
	endoscopes	endoscopes
	<ul> <li>Medical devices , including single,</li> </ul>	<ul> <li>Medical devices , including single,</li> </ul>
	dual or triple channeled stainless steel	dual or triple channeled stainless steel
	lumens that are: $1 < 527$ is $1 < 1$	lumens that are: $1 < 527$
	$\geq 0.77$ mm ID and $\leq 527$ mm in length	$\geq 0.77$ mm ID and $\leq 527$ mm in length $\geq 0.8$ mm ID and $\leq 542$ mm in length
	$\geq 0.8 \text{ mm ID and} \geq 542 \text{ mm in length}$	$\geq 0.8 \text{ mm ID and} \geq 542 \text{ mm in length}$
	<ul> <li>Medical devices with Dead end lumens</li> </ul>	• Medical devices with Dead end lumens
	that are $\geq 1.3$ mm ID and $\leq 73$ mm in	that are $\geq 1.3$ mm ID and $\leq 73$ mm in
	length	length
	• Devices with rigid non-metallic	• Devices with rigid non-metallic
	lumens (such as those used in	lumens (such as those used in
	endoscope sheaths, take-apart	endoscope sheaths, take-apart
	forceps and trocars) that are:	forceps and trocars) that are:
	$\geq$ 3 mm ID and $\leq$ 298 mm in length	$\geq$ 3 mm ID and $\leq$ 298 mm in length
	$\geq$ 4 mm ID and $\leq$ 424 mm in length	$\geq$ 4 mm ID and $\leq$ 424 mm in length
	V-PRO 1. 1 Plus. maX & maX2 Non	V-PRO 1, 1 Plus, maX & maX2 Non
	Lumen Cycle	Lumen Cycle
	Non-lumened devices including non-	Non-lumened devices including non-
	lumened rigid, semi-rigid and flexible	lumened rigid, semi-rigid and flexible
	endoscopes and non-lumened devices	endoscopes and non-lumened devices
	with diffusion-restricted spaces such as	with diffusion-restricted spaces such as
	the hinged portion of forceps and	the hinged portion of forceps and
	SCISSOFS.	SCISSOTS.
	V-PRO maX and maX 2 Flexible Cycle	V-PRO maX and maX 2 Flexible Cycle
	Load 1: Single or dual lumen surgical	Load 1: Single or dual lumen surgical
	flexible endoscopes (such as those used	flexible endoscopes (such as those used
	in ENT, Urology and Surgical Care) and	in ENT, Urology and Surgical Care) and
	bronchoscopes with a light cord (if not	bronchoscopes with a light cord (if not
	integral to endoscope) and mat with no	integral to endoscope) and mat with no
	adultional load.	additional load.
	contain either a single or dual	contain either a single or dual
	channel lumen that is $> 1 \text{ mm ID}$	channel lumen that is $> 1 \text{ mm ID}$
	and $< 1050$ mm in length	and $< 1050$ mm in length
	Load 2:	Load 2:
	<ul> <li>Non-lumened devices including</li> </ul>	<ul> <li>Non-lumened devices including non-</li> </ul>
	non-lumened rigid, semi-rigid and	lumened rigid, semi-rigid and flexible

Feature	Vis-U-All I Pouch	low Temper	ature St <b>1, K231</b> 5	terilization <b>500</b> )	Vis-U-All Low Temperature Sterilization Pouch (K222440)
	flexible en lumened de restricted s portion of • Single, d steel lume 100 mm i	ed devices with diffusion- ted spaces such as the hinged n of forceps and scissors le, dual or triple channel stainless lumen that is $\geq 0.48$ mm ID and $\leq$ mm in length.			<ul> <li>endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors</li> <li>Single, dual or triple channel stainless steel lumen that is ≥ 0.48 mm ID and ≤ 100 mm in length.</li> </ul>
	V-PRO max Non-lumened lumened rigi endoscopes a diffusion-res hinged portio	X 2 Fast No d devices ind d, semi-rigic and non-lum tricted space on of forceps	on Lum cluding r l and fle: ened dev es such a s and scis	en Cycle non- xible vices with ss the ssors.	<b>V-PRO maX 2 Fast Non Lumen Cycle</b> 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			e: g. ne) or dditive sses and rative g non- nts, non- ble lucted using ched tray) for a inted ducted of one uched tray) for a	
	Manufacturer Specialty			Lumens	
	Surgical Guide Resin	Formlabs	F F	$\geq 3 \text{ mm ID x}$ $\leq 30 \text{ mm L}$	
	BioMed Amber Resin	Formlabs	F		
	Dental LT Clear V2 Resin	Formlabs	D	$\geq 3 \text{ mm ID x}$ $\leq 30 \text{ mm L}$	
	BioMed Clear Resin	Formlabs	D	$\geq 3 \text{ mm ID x}$ $\leq 30 \text{ mm L}$	
	Clear MED610 Biocompatible	Stratasys	E	$\leq 20 \text{ mm L}$	
	Opaque MED615RGD	Stratasys	Е	$\geq 3 \text{ mm ID x}$ $\leq 20 \text{ mm L}$	
	MED620	Stratasys	Е	$\ge 3 \text{ mm ID x}$ $\le 20 \text{ mm L}$	

Feature	Vis-U-All Low Temperature Sterilization Pouch ( <b>proposed</b> , <b>K231500</b> )	Vis-U-All Low Temperature Sterilization Pouch (K222440)
	<b>STERRAD 100S Default Cycle</b> 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: $\geq 6 \text{ mm ID and } \leq 310 \text{ mm in length}$ Medical devices with a single stainless steel lumen with: $\geq 1 \text{ mm ID and } \leq 125 \text{ mm in length}$ $\geq 2 \text{ mm ID and } \leq 250 \text{ mm in length}$ $\geq 3 \text{ mm ID and } \leq 400 \text{ mm in length}$	<b>STERRAD 100S Default Cycle</b> 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: $\geq 6 \text{ mm ID and} \leq 310 \text{ mm in length}$ Medical devices with a single stainless steel lumen with: $\geq 1 \text{ mm ID and} \leq 125 \text{ mm in length}$ $\geq 2 \text{ mm ID and} \leq 250 \text{ mm in length}$ $\geq 3 \text{ mm ID and} \leq 400 \text{ mm in length}$
	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: $\geq 1 \text{ mm ID and} \leq 150 \text{ mm in length}$ $\geq 2 \text{ mm ID and} \leq 400 \text{ mm in length}$	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: $\geq 1 \text{ mm ID and} \leq 150 \text{ mm in length}$ $\geq 2 \text{ mm ID and} \leq 400 \text{ mm in length}$
	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: $\geq 1 \text{ mm ID}$ and $\leq 500 \text{ mm in length}$ Single channel polyethylene and Teflon (polytetrafluoroethylene) $\geq 1 \text{ mm ID}$ and $\leq 850 \text{ mm in length}$	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: $\geq 1 \text{ mm ID}$ and $\leq 500 \text{ mm in length}$ Single channel polyethylene and Teflon (polytetrafluoroethylene) $\geq 1 \text{ mm ID}$ and $\leq 850 \text{ mm in length}$
	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: $\geq 0.7$ mm ID and $\leq 500$ 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: $\geq 0.7$ mm ID and $\leq 500$ mm in length
	<b>STERRAD 100NX and 100NX with</b> <b>ALLClear Technology Flex Scope Cycle</b> Metal and nonmetal medical devices including instruments which have diffusion- restricted spaces, such as the hinged portion	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

Feature	Vis-U-All Low Temperature Sterilization	Vis-U-All Low Temperature Sterilization	
	of forceps and scissors	Pouch (K222440)	
	Medical Devices, including most flexible	Medical Devices, including most flexible	
	endoscopes, with:	endoscopes, with:	
	□ Single channel polyethylene and Teflon	□ Single channel polyethylene and Teflon	
	(polytetrainuoroetnytene) $> 1 \text{ mm ID}$ and $< 850 \text{ mm in length}$	(polytetraliuoroethylene) $> 1 \text{ mm ID}$ and $< 850 \text{ mm in length}$	
	STERRAD 100NX and 100NX with	STERRAD 100NX and 100NX with	
	ALLClear Technology Express Cycle	ALLClear Technology Express Cycle	
	(surfaces sterilization only) and instruments	(surfaces sterilization only) and instruments	
	which have diffusion- restricted spaces ,	which have diffusion- restricted spaces ,	
	such as the hinged portion of forceps and	such as the hinged portion of forceps and	
	scissors.	scissors.	
	STERRAD 100NX and 100NX with	STERRAD 100NX and 100NX with	
	ALLClear Technology Duo Cycle	ALLClear Technology Duo Cycle Medical	
	Medical devices including:	devices including:	
	channel of polyethylene and Teflon	channel of polyethylene and Teflon	
	(polytetrafluoroethylene) with $\geq 1 \text{ mm ID}$	(polytetrafluoroethylene) with $\geq 1 \text{ mm ID}$	
	and $\leq$ 875 mm in length	and $\leq$ 875 mm in length	
	• accessory devices that are normally	• accessory devices that are normally	
	use	use	
	• flexible endoscopes without lumens	• flexible endoscopes without lumens	
	Ethylene Oxide Sterilization		
	The V1s-U-All Low Temperature Starilization 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		
	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 expective at $120(+5)$ °E * >20%		
	• I nour exposure, at $130(\pm 3)$ F, $230\%$ RH using 100% FTO (750-790 mg/L)		
	• 4.5 hour exposure at $100(\pm 5)$ °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.		

Feature	Vis-U-All Low Temperature Sterilization Pouch ( <b>proposed</b> , <b>K231500</b> )	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	<ul> <li>Chevron end of pouches for ease of opening</li> <li>Chemical process indicator for EO</li> </ul>	<ul> <li>Chevron end of pouches for ease of opening</li> <li>Chemical process indicator for EO</li> </ul>	
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)
	<ul> <li>The Vis-U-All Low Temperature</li> <li>Sterilization Pouches/Tubing are</li> <li>sterilization containment pouches for use by</li> <li>health care providers to enclose:</li> <li>medical devices in a single or double</li> <li>pouch configuration</li> <li>trays* containing medical devices in a</li> <li>single or double pouch configuration</li> <li>small items requiring surface sterilization</li> <li>in a single pouch configuration within a</li> <li>tray</li> </ul>	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.
Intended	pouched	The following are the validated test conditions:
Intended Use / Indications for Use	<ul> <li>to be sterilized in the:</li> <li>Lumen, Non Lumen, Flexible, Fast Non Lumen and Fast Cycles of the V-PRO ® Low Temperature Sterilization Systems</li> <li>Default Cycle of the STERRAD** 100S Sterilizer</li> <li>Standard and Advanced Cycles of the STERRAD NX and NX with ALLClear** Technology Sterilizers</li> <li>Express, Standard, Flex Scope and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers</li> <li>**STERRAD and ALLClear are trademarks of Advanced Sterilization Products</li> </ul>	• 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.
	NOTE: Trays must be legally marketed for use in the V PRO Low Temperature or	

Feature	Vis-U-All Low Temperature Sterilization	Vis-U-All Low Temperature Sterilization
	Pouch (proposed, K231500)	Pouch (K092/45)
	STERRAD Sterilization Systems and	
	contain a vent surface area to tray volume $125 \pm 1$ is the theorem in the surface area to tray volume	
	ratio $\leq 0.155$ in-1 with the maximum	
	number of instrument organizers instaned.	
	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 Cvcle	
	• 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 imple channeled rigid and semi-rigid	
	configurations:	
	single or dual lumen devices	
	> 0.77 mm internal diameter (ID) and $< 410$	
	mm in length	
	$\geq 1.8 \text{ mm ID } x \leq 542 \text{ mm in length}$	
	triple lumen devices	
	$\geq 1.2 \text{ mm ID and} \leq 275 \text{ mm in length}$	
	$\geq 1.8 \text{ mm ID and} \leq 310 \text{ mm in length}$	
	Or	
	$\geq$ 2.8 mm ID and $\leq$ 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 auditional load. The flexible	
	• single or dual lumen device with lumens	
	that are $> 1 \text{ mm ID}$ and $< 990 \text{ mm in}$	

Footuro	Vis-U-All Low Temperature Sterilization	Vis-U-All Low Temperature Sterilization
reature	Pouch ( <b>proposed</b> , K231500)	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	
	following configurations:	
	$\sim 0.76 \text{ mm ID}$ and $< 222 \text{ mm in length}$	
	$\geq 0.70$ mm ID and $\leq 255$ mm in length	
	$\geq$ 1.0 mm ID and $\leq$ 2.54 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:	
	$\sim 0.77$ mm ID and $\leq 410$ mm in langth	
	$\geq 0.77$ mm ID and $\geq 410$ mm in length $\geq 1.8$ mm ID $x \leq 542$ mm in length	
	$\leq$ 1.6 IIIII ID X $\geq$ 342 IIIII III lengui • Triple channeled devices with steipless	
	steel lumens that are either:	
	$\geq 1.2 \text{ mm ID and } \leq 275 \text{ mm in length}$	
	1 8mm ID and 310mm in length	
	Or	
	$\geq 2.8 \text{ mm ID and} \leq 317 \text{ mm in length}$	
	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-	
	endoscones	
	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 $\geq$ 1.3 mm ID and $\leq$ 73 mm in	
	length	
	• Devices with rigid non-metallic	
	lumens (such as those used in	
	endoscope sheaths, take-apart	
	forceps and trocars) that are:	
	$\geq$ 3 mm ID and $\leq$ 298 mm in length	

Fosturo	Vis-U-All Low Temperature Sterilization	Vis-U-All Low Temperature Sterilization
Feature	Pouch (proposed, K231500)	Pouch (K092745)
	$\geq$ 4 mm ID and $\leq$ 424 mm in length	
	V DDO 1 1 Dlug moV & moV2 Non	
	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	
	additional load	
	The flexible endoscopes may	
	contain either a single or dual	
	channel lumen that is $> 1 \text{ mm ID}$	
	and $< 1050 \text{ mm}$ in length	
	Load 2:	
	• Non-lumened devices including	
	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 $20.48 \text{ mm}$ ID and $\leq$	
	steel fumen that is $\geq 0.48$ mm iD and $\geq 100$ mm in length	
	100 min in length.	
	V-PRO maX 2 Fast Non Lumen Cycle	
	Non-lumened devices including non-	
	lumened rigid, semi-rigid and flexible	
	diffusion restricted spaces such as the	
	hinged portion of forceps and scissors.	
	C I I I I I I I I I I I I I I I I I I I	
	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	
	procedures *	
	or	
	Non-lumened instruments including non-	
	lumened general medical instruments, non-	
	lumened rigid, semi-rigid and flexible	
	endoscopes.**	
	a validation load consisting of pouched	

E (	Vis-U-All Low Temperature Sterilization		terilization	Vis-U-All Low Temperature Sterilization	
Feature	Pouch (proposed, K231500)			500)	Pouch (K092745)
	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 valida	ation load co	nsisting o	of one	
	pouched instr	rument tray o	or one po	uched	
	instrument tra	ay or one pou	ich with		
	guide(s)/mod	el(s) (with or	r without	tray) for a	
	total weight o	of 11 lbs $(5 \text{ k})$	g).		
			G		
	Material	Manufacturer	Specialty Cycle	Lumens	
	Surgical Guide Resin	Formlabs	F	$\geq 3 \text{ mm ID x}$ $\leq 30 \text{ mm L}$	
	BioMed Amber Resin	Formlabs	F	≥3 mm ID x ≤30 mm L	
	Dental LT Clear	Formlabs	D	$\geq 3 \text{ mm ID x}$	
	V2 Resin		_	$\leq 30 \text{ mm L}$	
	Resin	Formlabs	D	$\leq 30 \text{ mm L}$	
	Biocompatible	Stratacyc	Б	$\geq 3 \text{ mm ID x}$	
	Clear MED610	Stratasys	Б	≤20 mm L	
	Opaque	Stratasys	F	$\geq$ 3 mm ID x	
	MED615RGD	Diratasys	Ľ	≤20 mm L	
	VeroGlaze <sup>TM</sup>	Stratasys	Е	$\geq 3 \text{ mm ID } x$	
	MED620			≤20 mm L	
	STERRAD Metal and noi including ins restricted spa of forceps an Metal and noi with: $\geq 6 \text{ mm ID ar}$ Medical devi lumen with: $\geq 1 \text{ mm ID ar}$ $\geq 2 \text{ mm ID ar}$ $\geq 3 \text{ mm ID ar}$	<b>100S Defau</b> onmetal med struments whaces, such as ad scissors. onmetal lumo ad $\leq 310$ mm ices with a s ad $\leq 125$ mm ad $\leq 250$ mm ad $\leq 400$ mm	It Cycle ical deviation have the hing ened instanting in length ingle stanting in length in length in length	ices e diffusion- ged portion truments h inless steel gth gth	
	STERRAD Technology Metal and no including ins restricted spa of forceps an Medical devi lumen with: ≥ 1 mm ID a ≥ 2 mm ID a	NX and NX Standard C onmetal med acres, such as ad scissors. acces with a s and $\leq 150$ mm and $\leq 400$ mm	with A Cycle ical devi nich have the hing ingle sta n in leng n in leng	LLClear ices e diffusion- ged portion inless steel gth gth	
	STERRAD Technology	NX and NX	. with A Cycle	LLClear	
	Metal and no	nmetal med	ical devi	ices	
	including instruments which have diffusion-				

Footure	Vis-U-All Low Temperature Sterilization	Vis-U-All Low Temperature Sterilization
reature	Pouch ( <b>proposed</b> , <b>K231500</b> )	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: $\sum_{i=1}^{n} 1 \leq 500$ mm is bouth	
	$\geq$ 1 mm ID and $\leq$ 500 mm in length	
	(nolytetroflycroethylone)	
	(polytetranuoroethylene) $\geq 1 \text{ mm ID and } \leq 850 \text{ mm in langth}$	
	$\geq 1$ min iD and $\geq 850$ min 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:	
	$\geq 0.7 \text{ mm ID and} \leq 500 \text{ mm in length}$	
	STERRAD 100NY and 100NY with	
	ALL Clear Technology Fley Scone 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)	
	$\geq 1 \text{ mm ID and} \leq 850 \text{ mm in length}$	
	STERRAD 100NX and 100NX with	
	ALL Clear 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 IOUNA and IOUNA with	
	Medical devices including:	
	most flexible endoscopes with a single	
	channel of polyethylene and Teflon	
	$(polytetrafluoroethylene)$ with $\geq 1 \text{ mm ID}$	
	and $\leq 875$ 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	Vis-U-All Low Temperature Sterilization
	Pouch (proposed, K231500)	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 athylene 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 $100(\pm 5)$ °F, *	
	>30% RH using 100% ETO (750-790	
	mg/L)	
	* $\pm$ 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	<ul> <li>Chevron end of pouches for ease of</li> </ul>	<ul> <li>Chevron end of pouches for ease of</li> </ul>
Features	opening	opening
	Chemical process indicator for EO	Chemical process indicator for EO
Maintenance of Sterility	l year	l year
Materials of	Tyvek and plastic	Tyvek and plastic
Construction		
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	Worst case test articles shall be	
Pouches (including pouched trays	reproducibly sterilized under worst case <sup>1</sup> / <sub>2</sub>	DASS
and, if applicable, pouches placed	cycle conditions for the 136L V-PRO	PASS
within a tray):	Sterilizer Specialty Cycle	

## 8. <u>Conclusion</u>

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.