August 7, 2023

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

Re: K231501
Trade/Device Name: PRO-LITE Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K231501

Device Name
PRO-LITE Sterilization Trays

Indications for Use *(Describe)*
The PRO-LITE Sterilization Trays are used to contain medical devices for sterilization in the following Cycles:

- Lumen, Non Lumen, Flexible, Fast Non Lumen, 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
- Standard, Flex Scope, Express and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers

*STERRAD and ALLClear are trademarks of Advanced Sterilization Products

Prior to placing in the Sterilizer, the trays must either be:

- wrapped with a legally marketed sterilization wrap for use in the Sterilizers listed above
  or
- placed inside a legally marketed pouch for enclosing trays in the Sterilizers listed above

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

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

V-PRO 60 and s2 Lumen Cycle:

- Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Non-lumened devices including non-lumened rigid and semi-rigid endoscopes
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes with the following configurations:
  - Single or dual channeled devices with stainless steel lumens that are:
    - $\geq$ 0.77 mm ID and $\leq$ 410 mm in length
    - $\geq$ 1.8 mm ID x $\leq$ 542 mm in length
  - Triple channeled devices with stainless steel lumens that are either:
    - $\geq$ 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 60 and s2 Non Lumen Cycle:
Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

V-PRO 60 and s2 Flexible Cycle:
Load 1: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a:

- Single or dual lumen device with lumens that are $\geq$ 1 mm ID and $\leq$ 990 mm in length

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

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

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

V-PRO s2 Fast Cycle:

- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes, and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps and scissors.
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
  - Single or dual channeled devices with stainless steel lumens
    - ≥ 0.77 mm ID and ≤ 410 mm in length
    - ≥ 1.8 mm ID and ≤ 542 mm in length
  - Triple channeled devices with stainless steel lumens
    - ≥ 1.2 mm ID and ≤ 275 mm in length
    - ≥ 1.8 mm ID and ≤ 310 mm in length

      or
    - ≥ 2.8 mm ID and ≤ 317 mm in length

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

V-PRO 1, 1 Plus, maX, and maX 2 Lumen Cycle:

- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Medical devices, including single, dual or triple channeled stainless steel lumens that are:
  - ≥ 0.77 mm ID and ≤ 527 mm in length
  - ≥ 0.8 mm ID and ≤ 542 mm in length
  - ≥ 0.48 mm ID and ≤ 100 mm in length
- Medical devices with dead end stainless steel lumens that are ≥ 1.3 mm ID and ≤ 73 mm in length
- 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 Plus, maX, and maX 2 Non Lumen Cycle:
Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors

V-PRO maX, and maX 2 Flexible Cycle:
Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain either a single or dual lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
Load 2:

- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Single, dual or triple channel stainless steel lumens that are ≥ 0.48 mm ID and ≤ 100 mm in length

Intended Sterilization Cycles and Intended Tray Loads for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050

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 (eg. 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 intrument try or one pouch with guide(s)/model(s) (with or without tray) for a total weight of 11 lbs (5kg).

Material	Manufacturer	Specialty Cycle	Lumens
Surgical Guide Resin	Formlabs	F	$\geq$ 3 mm ID and $\leq$ 30 mm L
Biomed Amber Resin	Formlabs	F	$\geq$ 3 mm ID and $\leq$ 30 mm L
Dental LT Clear V2 Resin	Formlabs	D	$\geq$ 3 mm ID and $\leq$ 30 mm L
Biomed Clear Resin	Formlabs	D	$\geq$ 3 mm ID and $\leq$ 30 mm L
Biocompatible Clear MED610	Stratasys	E	$\geq$ 3 mm ID and $\leq$ 20 mm L
Biocompatible Opaque Med615RGD	Stratasys	E	$\geq$ 3 mm ID and $\leq$ 20 mm L
Veroglaze MED620	Stratasys	E	$\geq$ 3 mm ID and $\leq$ 20 mm L

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

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 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

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

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 mm ID and $\leq$ 150 mm in length
- $\geq$ 2 mm ID and $\leq$ 400 mm in length

STERRAD NX and NX with ALLClear Technology Advanced Cycle:
Metal and non-metal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors
Medical devices with:
- a single stainless steel lumen with:

- ≥ 1 mm ID and ≤ 500 mm in length
- single channel polyethylene and Teflon (polytetrafluoroethylene)
  - ≥ 1mm ID and ≤ 850 mm in length

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

STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle:
Metal and nonmetal medical devices including instruments with have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
Medical devices with a single stainless steel lumen with:
- ≥ 0.7 mm ID and ≤ 500 mm in length

STERRAD 100NX and 100NX with ALLClear Technology Flex Scope Cycle:
Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
Medical devices, including most flexible endoscopes, with:
- Single channel polyethylene and Teflon (polytetrafluoroethylene)
  - ≥ 1mm ID and ≤ 850 mm in length

STERRAD 100NX and 100NX with ALLClear Technology Express Cycle:
Metal and nonmetal devices surfaces and instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

STERRAD 100NX and 100NX with ALLClear Technology Duo Cycle:
Medical devices including:
- most flexible endoscopes with a single channel of polyethylene and Teflon (polytetrafluoroethylene) with ≥ 1 mm ID and ≤ 875 mm in length
- accessory devices that are normally connected to a flexible endoscope during use
- flexible endoscopes without lumens

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

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

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

Model	Description (to fit Length" x Width" Tray)
VP0071	13 x 4.5
VP0072	19 x 4.5
VP0073	25 x 4.5
VP0074	13 x 7.75
VP0075	19 x 7.75
VP0076	27 x 7.75

VP0077	12 x 11.75
VP0078	25 x 11.75
VP0079	25 x 14

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.

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

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

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

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

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

510(k) Summary
For K231501
PRO-LITE™ Sterilization Tray

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: August 3, 2023

1. Device Name

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

2. Predicate Device

PRO-LITE Sterilization Tray, K222440

3. Description of Device

The PRO-LITE Sterilization Trays contain medical devices for sterilization in the V-PRO Low Temperature Sterilization Systems:

- V-PRO 1 Low Temperature Sterilization System,
- V-PRO 1 Plus Low Temperature Sterilization System,
- V-PRO maX Low Temperature Sterilization System,
- V-PRO maX 2 Low Temperature Sterilization System
- V-PRO 60 Low Temperature Sterilization System and
- V-PRO s2 Low Temperature Sterilization System

and the following STERRAD Sterilizers and cycles:

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

The trays are available in various sizes, outlined in **Table 5-1,** to accommodate the loads to be processed. The proposed trays are identical in design to the predicate Sterilization Tray (K222440) and are composed of a base and a lid. The lid includes clamping mechanisms designed to secure the lid onto the base. There are numerous holes in the base and lid for sterilant penetration. The tray is categorized as a cassette and requires complete enclosure in a legally-marketed sterilization wrap or pouch to maintain sterility of the enclosed devices. Both the base and the lid for the proposed tray are made of a mineral-filled polypropylene material.

Table 5-1. External Dimensions of Tray Line

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

Optional instrument organizers are provided as accessories to the trays and allow stabilization of various cylindrical medical devices during processing. **Table 5-2** lists the organizer sizes. The organizers are either "blank" and are used to partition the tray or have a device holding portion into which the devices are inserted. At the organizer base is a flapped groove that is used to position the organizer within a PRO-LITE Sterilization Tray.

Table 5.2. Instrument Organizer Model Numbers

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

Optional sterilization mats are provided as accessories to the trays. The mats, which are used to cushion and stabilize devices placed into the trays, are available in sizes as shown in **Table 5-3** to fit the nine PRO-LITE Sterilization Trays. The mats are a diamond grid design with "fingers" that extend from each corner of the diamond and at the midpoint of each diamond side. The fingers cushion and stabilize instruments, helping to prevent the instruments from freely moving in the tray during packaging, sterilization and storage. The cushioning and stabilization qualities help protect delicate instruments placed into the trays.

Table 5-3. Silicone Mat Model Numbers

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

The purpose of this submission is to add or expand claims for the use of these tray models in the following sterilizer cycles 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 PRO-LITE™ Sterilization Trays are used to contain medical devices for sterilization in the following Cycles:

- 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 100 NX with ALLClear Technology Sterilizers

*STERRAD and ALLClear are trademarks of Advanced Sterilization Products

Prior to placing in the Sterilizer, the trays must either be:

- wrapped with a legally marketed sterilization wrap for use in the Sterilizers listed above.
  or
- placed inside a legally marketed pouch for enclosing trays in the Sterilizers listed above.

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

Tray Models	Intended Sterilization Cycles	Intended Tray Load
VP0045 VP0046 VP0047 VP0048 VP0049 VP0050 VP0051 VP0052	V-PRO 60 and s2 Lumen Cycle	• Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes with the following configurations: o Single or dual lumen devices with stainless steel lumens that are: ▪ ≥ 0.77 mm ID and ≤ 410 mm in length ▪ ≥ 1.8 mm ID and ≤ 542 mm in length o Triple lumen devices with stainless steel lumens ▪ ≥ 1.2 mm ID and ≤ 275 mm in length ▪ ≥ 1.8 mm ID and ≤ 310 mm in length or ▪ ≥ 2.8 mm ID and ≤ 317 mm in length
	V-PRO 60 and s2 Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with

Tray Models	Intended Sterilization Cycles	Intended Tray Load
		diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	V-PRO 60 and s2 Flexible Cycle	Load 1: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a: • Single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length Load 2: Non-lumened devices including non-lumened rigid, semi-rigid, and flexible endoscopes and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors. Medical devices, including rigid and semi-rigid endoscopes with the following configurations: • ≥ 0.76 mm ID and ≤ 233 mm in length • ≥ 1.0 mm ID and ≤ 254 mm in length • ≥ 1.8 mm ID and ≤ 542 mm in length
VP0045 VP0046 VP0047 VP0048 VP0049	V-PRO s2 Fast Cycle	• Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes, and non-lumened devices with diffusion restricted areas such as the hinged portion of forceps or scissors. • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: o Single or dual lumen channeled devices with stainless steel lumens ▪ ≥ 0.77 mm ID and ≤ 410 mm in length ▪ ≥ 1.8 mm ID and ≤ 542 mm in length o Triple 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
VP0045 VP0046 VP0047 VP0048 VP0049 VP0050 VP0051 VP0052 VP0053	V-PRO 1, 1 Plus, maX, and maX 2 Lumen Cycle	• Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices, including single, dual or triple channeled stainless steel lumens that are: o ≥ 0.77 mm ID and ≤ 527 mm in length o ≥ 0.8 mm ID and ≤ 542 mm in length o ≥ 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: o ≥ 3 mm ID and ≤ 298 mm in length o ≥ 4 mm ID and ≤ 424 mm in length
	V-PRO 1 Plus, maX, and maX	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with

<table>
<tr><th>Tray Models</th><th>Intended Sterilization Cycles</th><th>Intended Tray Load</th></tr>
<tr><td rowspan="2"></td><td>2 Non Lumen Cycle</td><td>diffusion-restricted spaces such as the hinged portion of forceps and scissors.</td></tr>
<tr><td>V-PRO maX, and maX 2 Flexible Cycle</td><td>Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain either a single or dual lumen that is ≥ 1 mm ID and ≤ 1050 mm in length

Load 2:
• Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors
• Single, dual or triple stainless steel lumens that are ≥ 0.48 mm ID and ≤ 100 mm in length</td></tr>
<tr><td rowspan="2">VP0045
VP0046
VP0047
VP0048
VP0049
VP0050</td><td>V-PRO maX 2 Fast Non Lumen Cycle</td><td>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>
<tr><td>V-PRO maX 2 Specialty Cycle</td><td>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 (2.3kg) 3D printed material.
**The validation studies were conducted using a validation load consisting of one pouched instrument tray or one pouch with guide(s)/model(s) (with or without tray) for a total weight of 11 lbs (5kg).
<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>
<tr><td>BioMed Amber Resin</td><td>Formlabs</td><td>F</td><td>≥3 mm ID x ≤30 mm L</td></tr>
<tr><td>Dental LT Clear V2 Resin</td><td>Formlabs</td><td>D</td><td>≥3 mm ID x ≤30 mm L</td></tr>
<tr><td>BioMed Clear Resin</td><td>Formlabs</td><td>D</td><td>≥3 mm ID x ≤30 mm L</td></tr>
</table></td></tr>
</table>

Tray Models	Intended Sterilization Cycles	Intended Tray Load
		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
VP0045 VP0046 VP0047 VP0048 VP0049 VP0050 VP0051 VP0052	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
VP0045 VP0046 VP0048 VP0049	STERRAD NX and NX with ALLClear Technology Standard Cycle	Metal and non-metal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 150 mm in length • ≥ 2 mm ID and ≤ 400 mm in length
	STERRAND NX and NX with ALLClear Technology Advanced Cycle	Metal and non-metal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors Medical devices, including most flexible endoscopes, with: o a single stainless steel lumen with: o ≥ 1 mm ID and ≤ 500 mm in length o single channel polyethylene and Teflon (polytetrafluoroethylene) o ≥ 1mm ID and ≤ 850 mm in length
VP0045 VP0046 VP0047 VP0048 VP0049 VP0051 VP0052 VP0053	STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle	Metal and nonmetal medical devices including instruments with have diffusion-restricted spaces, such as the hinged portion of forceps and scissors Medical devices with a single stainless steel lumen with: • ≥ 0.7 mm ID and ≤ 500 mm in length
	STERRAD 100NX and 100NX with ALLClear Technology Flex Scope Cycle	Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices, including most flexible endoscopes, with: • Single channel polyethylene and Teflon (polytetrafluoroethylene) o ≥ 1mm ID and ≤ 850 mm in length
	STERRAD 100NX and 100NX with	Metal and nonmetal devices surfaces and instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors.

Tray Models	Intended Sterilization Cycles	Intended Tray Load
	ALLClear Technology Express Cycle	
	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

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

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

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

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

5. Summary of Technical Characteristics

The proposed PRO-LITE sterilization trays, sterilization mats and instrument organizers are identical in composition to the claimed predicate devices. The technical characteristics are summarized below in **Table 5-5**.

Table 5-5. Summary of Tray Physical Description and Technological Properties

Feature	PRO-LITE Sterilization Tray (proposed / K231501)	PRO-LITE Sterilization Tray (predicate / K222440)	Comparison
Intended Use / Indications for Use	The PRO-LITE Sterilization Trays are used to contain medical devices for sterilization in the following Cycles: • Lumen, Non Lumen, Flexible, Fast Non Lumen, 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 • Standard, Flex Scope, Express and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers *STERRAD and ALLClear are trademarks of Advanced Sterilization Products Prior to placing in the Sterilizer, the trays must either be: • wrapped with a legally marketed sterilization wrap for use in the Sterilizers listed above or • placed inside a legally marketed pouch for enclosing trays in the Sterilizers listed above. The PRO-LITE Sterilization Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap or pouch in order to maintain sterility of the enclosed medical instruments. Intended Sterilization Cycles and Intended Tray Loads for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052 <u>V-PRO 60 and s2 Lumen Cycle:</u> • Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors	The PRO-LITE Sterilization Trays are used to contain medical devices for sterilization in the following Cycles: • Lumen, Non Lumen, Flexible, Fast Non Lumen and Fast Cycles of the V-PRO Low Temperature Sterilization Systems • Default Cycle of the STERRAD®* 100S Sterilizer • Standard and Advanced Cycles of the STERRAD NX and NX with ALLClear Technology Sterilizers • Standard, Flex Scope, Express and DUO Cycles of the STERRAD 100NX and 100NX with ALLClear Technology Sterilizers *STERRAD and ALLClear are trademarks of Advanced Sterilization Products Prior to placing in the Sterilizer, the trays must either be: • wrapped with a legally marketed sterilization wrap for use in the Sterilizers listed above or • placed inside a legally marketed pouch for enclosing trays in the Sterilizers listed above. The PRO-LITE Sterilization Trays are not intended to maintain sterility; they are intended to be used in conjunction with a validated, FDA-cleared sterilization wrap or pouch in order to maintain sterility of the enclosed medical instruments. Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052 <u>V-PRO 60 and s2 Lumen Cycle:</u> • Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors	Additional claims have been added for the V-PRO maX 2 Specialty Cycle – all other indications for use are the same

Feature	PRO-LITE Sterilization Tray (proposed / K231501)	PRO-LITE Sterilization Tray (predicate / K222440)	Comparison
	• Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes with the following configurations: o Single or dual channeled devices with stainless steel lumens that are: ▪ ≥ 0.77 mm ID and ≤ 410 mm in length ▪ ≥ 1.8 mm ID x ≤ 542 mm in length o Triple channeled devices with stainless steel lumens that are either: ▪ ≥ 1.2 mm ID and ≤ 275 mm in length ▪ ≥ 1.8 mm ID and ≤ 310 mm in length or ▪ ≥ 2.8 mm ID and ≤ 317 mm in length V-PRO 60 and s2 Non Lumen Cycle: Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors. V-PRO 60 and s2 Flexible Cycle: Load 1: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a: • Single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length Load 2: Non-lumened devices including non-lumened rigid, semi-rigid, and flexible endoscopes and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors. Medical devices, including rigid and semi-rigid endoscopes with the following configurations: • ≥ 0.76 mm ID and ≤ 233 mm in length • ≥ 1.0 mm ID and ≤ 254 mm in length • ≥ 1.8 mm ID and ≤ 542 mm in length Intended Sterilization Cycles and Intended Tray Loads for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049	• Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes with the following configurations: o Single or dual channeled devices with stainless steel lumens that are: ▪ ≥ 0.77 mm ID and ≤ 410 mm in length ▪ ≥ 1.8 mm ID x ≤ 542 mm in length o Triple channeled devices with stainless steel lumens that are: ▪ ≥ 1.2 mm ID and ≤ 275 mm in length ▪ ≥ 1.8 mm ID and ≤ 310 mm in length or ▪ ≥ 2.8 mm ID and ≤ 317 mm in length V-PRO 60 and s2 Non Lumen Cycle: Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors. V-PRO 60 and s2 Flexible Cycle: Load 1: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a: • Single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length Load 2: Non-lumened devices including non-lumened rigid, semi-rigid, and flexible endoscopes and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors. Medical devices, including rigid and semi-rigid endoscopes with the following configurations: • ≥ 0.76 mm ID and ≤ 233 mm in length • ≥ 1.0 mm ID and ≤ 254 mm in length • ≥ 1.8 mm ID and ≤ 542 mm in length Intended Sterilization Cycle and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049	

Feature	PRO-LITE Sterilization Tray (proposed / K231501)	PRO-LITE Sterilization Tray (predicate / K222440)	Comparison
	V-PRO s2 Fast Cycle: • Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes, and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps and scissors. • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: o Single or dual channeled devices with stainless steel lumens ▪ ≥ 0.77 mm ID and ≤ 410 mm in length ▪ ≥ 1.8 mm ID and ≤ 542 mm in length o Triple channeled devices with stainless steel lumens ▪ ≥ 1.2 mm ID and ≤ 275 mm in length ▪ ≥ 1.8 mm ID and ≤ 310 mm in length ▪ ≥ 2.8 mm ID and ≤ 317 mm in length Intended Sterilization Cycles and Intended Tray Loads for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052, VP0053 V-PRO 1, 1 Plus, maX, and maX 2 Lumen Cycle: • Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices, including single, dual or triple channeled stainless steel lumens that are: o ≥ 0.77 mm ID and ≤ 527 mm in length o ≥ 0.8 mm ID and ≤ 542 mm in length o ≥ 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: o ≥ 3 mm ID and ≤ 298 mm in length o ≥ 4 mm ID and ≤ 424 mm in length V-PRO 1 Plus, maX, and maX 2 Non Lumen Cycle:	V-PRO s2 Fast Cycle: • Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes, and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps and scissors. • Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations: o Single or dual channeled devices with stainless steel lumens ▪ ≥ 0.77 mm ID and ≤ 410 mm in length ▪ ≥ 1.8 mm ID and ≤ 542 mm in length o Triple channeled devices with stainless steel lumens that are either ▪ ≥ 1.2 mm ID and ≤ 275 mm in length ▪ ≥ 1.8 mm ID and ≤ 310 mm in length ▪ ≥ 2.8 mm ID and ≤ 317 mm in length Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052, VP0053 V-PRO 1, 1 Plus, maX, and maX 2 Lumen Cycle: • Non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Medical devices, including single, dual or triple channeled stainless steel lumens that are: o ≥ 0.77 mm ID and ≤ 527 mm in length o ≥ 0.8 mm ID and ≤ 542 mm in length o ≥ 0.48 mm ID and ≤ 100 mm in length • Medical devices with dead end stainless steel lumens that are ≥ 1.3 mm ID and ≤ 73 mm in length • Devices with rigid non-metallic lumens (such as those used in endoscope sheaths, take-apart forceps and trocars) that are: o ≥ 3 mm ID and ≤ 298 mm in length o ≥ 4 mm ID and ≤ 424 mm in length V-PRO 1 Plus, maX, and maX 2 Non Lumen Cycle:	

Feature	PRO-LITE Sterilization Tray (proposed / K231501)	PRO-LITE Sterilization Tray (predicate / K222440)	Comparison
	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors V-PRO maX, and maX 2 Flexible Cycle: Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain either a single or dual lumen that is ≥ 1 mm ID and ≤ 1050 mm in length Load 2: • Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Single, dual or triple channel stainless steel lumens that are ≥ 0.48 mm ID and ≤ 100 mm in length Intended Sterilization Cycles and Intended Tray Loads for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050 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-	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors V-PRO maX, and maX 2 Flexible Cycle: Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain either a single or dual lumen that is ≥ 1 mm ID and ≤ 1050 mm in length Load 2: • Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Single, dual or triple channel stainless steel lumens that are ≥ 0.48 mm ID and ≤ 100 mm in length V-PRO maX 2 Fast Non Lumen Cycle: Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.	

Feature	PRO-LITE Sterilization Tray (proposed / K231501)	PRO-LITE Sterilization Tray (predicate / K222440)	Comparison
	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 (2.3kg) 3D printed material. **The validation studies were conducted using a validation load consisting of one pouched instrument tray or one pouch with guide(s)/model(s) (with or without tray) for a total weight of 11 lbs (5kg). • Formlabs Surgical Guide Resin, Specialty Cycle F, Lumens ≥ 3 mm ID x ≤ 30 mm L • Formlabs BioMed Amber Resin, Specialty Cycle F, Lumens ≥ 3 mm ID x ≤ 30 mm L • Formlabs Dental LT Clear V2 Resin, Specialty Cycle D, Lumens ≥ 3 mm ID x ≤ 30 mm L • Formlabs BioMed Clear Resin, Specialty Cycle D, Lumens ≥ 3 mm ID x ≤ 30 mm L • Stratasys Biocompatible Clear MED610, Specialty Cycle E, Lumens ≥ 3 mm ID x ≤ 20 mm L • Stratasys Biocompatible Clear MED610, Specialty Cycle E, Lumens ≥ 3 mm ID x ≤ 20 mm L • Stratasys Biocompatible Opaque MED615 RGD, Specialty Cycle E, Lumens ≥ 3 mm ID x ≤ 20 mm L Stratasys VeroGlaze MED620, Specialty Cycle E, Lumens ≥ 3 mm ID x ≤ 20 mm L Intended Sterilization Cycles and Intended Tray Loads for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052 <u>STERRAD 100S Default Cycle:</u> Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Metal and nonmetal lumened instruments with • ≥ 6 mm ID and ≤ 310 mm in length	Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052 <u>STERRAD 100S Default Cycle:</u> Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Metal and nonmetal lumened instruments with • ≥ 6 mm ID and ≤ 310 mm in length	

Feature	PRO-LITE Sterilization Tray (proposed / K231501)	PRO-LITE Sterilization Tray (predicate / K222440)	Comparison
	Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 125 mm in length • ≥ 2 mm ID and ≤ 250 mm in length • ≥ 3 mm ID and ≤ 400 mm in length Intended Sterilization Cycles and Intended Tray Loads for Tray Models: VP0045, VP0046, VP0048, VP0049 <u>STERRAD NX and NX with ALLClear Technology Standard Cycle:</u> Metal and non-metal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 150 mm in length • ≥ 2 mm ID and ≤ 400 mm in length <u>STERRAND NX and NX with ALLClear Technology Advanced Cycle:</u> Metal and non-metal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors Medical devices, including most flexible endoscopes, with: ○ a single stainless steel lumen with: ○ ≥ 1 mm ID and ≤ 500 mm in length ○ single channel polyethylene and Teflon (polytetrafluoroethylene) ○ ≥ 1mm ID and ≤ 850 mm in length Intended Sterilization Cycles and Intended Tray Loads for Tray Models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0051, VP0052, VP0053 <u>STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle:</u> Metal and nonmetal medical devices including instruments with have diffusion-restricted spaces, such as the hinged portion of forceps and scissors Medical devices with a single stainless steel lumen with:	Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 125 mm in length • ≥ 2 mm ID and ≤ 250 mm in length • ≥ 3 mm ID and ≤ 400 mm in length Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0048, VP0049 <u>STERRAD NX and NX with ALLClear Technology Standard Cycle:</u> Metal and non-metal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices with a single stainless steel lumen with: • ≥ 1 mm ID and ≤ 150 mm in length • ≥ 2 mm ID and ≤ 400 mm in length <u>STERRAND NX and NX with ALLClear Technology Advanced Cycle:</u> Metal and non-metal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors Medical devices, including most flexible endoscopes, with: ○ a single stainless steel lumen with: ○ ≥ 1 mm ID and ≤ 500 mm in length ○ single channel polyethylene and Teflon (polytetrafluoroethylene) ○ ≥ 1mm ID and ≤ 850 mm in length Intended Sterilization Cycles and Intended Tray Load for Tray Models: VP0045, VP0046, VP0048, VP0049, VP0051, VP0052, VP0053 <u>STERRAD 100NX and 100NX with ALLClear Technology Standard Cycle:</u> Metal and nonmetal medical devices including instruments with have diffusion-restricted spaces, such as the hinged portion of forceps and scissors Medical devices with a single stainless steel lumen with:	

Feature	PRO-LITE Sterilization Tray (proposed / K231501)	PRO-LITE Sterilization Tray (predicate / K222440)	Comparison
	• ≥ 0.7 mm ID and ≤ 500 mm in length STERRAD 100NX and 100NX with ALLClear Technology Flex Scope Cycle: Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices, including most flexible endoscopes, with: • Single channel polyethylene and Teflon (polytetrafluoroethylene) ○ ≥ 1mm ID and ≤ 850 mm in length STERRAD 100NX and 100NX with ALLClear Technology Express Cycle: Metal and nonmetal devices surfaces and instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. STERRAD 100NX and 100NX with ALLClear Technology Duo Cycle: Medical devices including: • most flexible endoscopes with a single channel of polyethylene and Teflon (polytetrafluoroethylene) with ≥ 1 mm ID and ≤ 875 mm in length • accessory devices that are normally connected to a flexible endoscope during use • flexible endoscopes without lumens	• ≥ 0.7 mm ID and ≤ 500 mm in length STERRAD 100NX and 100NX with ALLClear Technology Flex Scope Cycle: Metal and nonmetal medical devices including instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. Medical devices, including most flexible endoscopes, with: • Single channel polyethylene and Teflon (polytetrafluoroethylene) ○ ≥ 1mm ID and ≤ 850 mm in length STERRAD 100NX and 100NX with ALLClear Technology Express Cycle: Metal and nonmetal devices surfaces and instruments which have diffusion-restricted spaces, such as the hinged portion of forceps and scissors. STERRAD 100NX and 100NX with ALLClear Technology Duo Cycle: Medical devices including: • most flexible endoscopes with a single channel of polyethylene and Teflon (polytetrafluoroethylene) with ≥ 1 mm ID and ≤ 875 mm in length • accessory devices that are normally connected to a flexible endoscope during use • flexible endoscopes without lumens	
Vent to Volume Ratio	All trays are the same: 0.135 in^{-1}	All trays are the same: 0.135 in^{-1}	Same
Tray Composition	Mineral-filled polypropylene, stainless steel	Mineral-filled polypropylene, stainless steel	Same
Instrument Organizer Composition	Medical Grade Silicone, USP grade VI	Medical Grade Silicone, USP grade VI	Same
Mat Composition	Medical Grade Silicone, USP grade VI	Medical Grade Silicone, USP grade VI	Same

6. Summary of Non-clinical Tests

Performance testing to demonstrate substantial equivalence to the predicate has been completed and is summarized in **Table 5-5** below.

Table 5-5. Summary of Non-clinical Testing

Test	Result	Conclusion
Demonstration of Effective Sterilant Penetration	Cycle specific test articles shall be reproducibly sterilized under ½ cycle conditions for the V-PRO maX 2 Specialty Cycle	PASS

7. Conclusion

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