January 3, 2019

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

Re: K183301
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: November 26, 2018
Received: November 27, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Elizabeth F. Claverie -S

For Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K183301

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 and Fast Cycles of the V-PRO® Low Temperature Sterilization Systems

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, VP0050, VP0051, VP0052

V-PRO 60 & s2 Lumen Cycle
- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Non-lumened devices including non-lumened rigid and semi-rigid endoscopes
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
  - single or dual lumen devices
    - ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm in length
  - triple lumen devices
    - ≥ 1.2 mm ID and ≤ 275 mm in length
    - ≥ 1.8 mm ID and ≤ 310 mm in length
      or
    - ≥ 2.8 mm ID and ≤ 317 mm in length

V-PRO 60 & s2 Non Lumen Cycle
Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

V-PRO 60 & s2 Flexible Cycle
Load 1: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a:
- single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length

Load 2: Non-lumened devices including non-lumened rigid, semi-rigid, and flexible endoscopes and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors. Medical devices, including rigid and semi-rigid endoscopes, with the following dimensions:
- ≥ 2 mm ID and ≤ 400 mm in length
- ≥ 0.76 mm ID and ≤ 233 mm in length
- ≥ 1.0 mm ID and ≤ 254 mm in length

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

V-PRO s2 Fast Cycle

- Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes, and non-lumened devices with diffusion-restricted areas such as the hinged portion of forceps or scissors.
- Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
  - Single or dual channeled devices with stainless steel lumens that are ≥ 0.77 mm ID and ≤ 410 mm in length
  - Triple channeled devices with stainless steel lumens that are either:
    - ≥ 1.2 mm ID and ≤ 275 mm in length
    - ≥ 1.8 mm ID and ≤ 310 mm in length
      or
    - ≥ 2.8 mm ID and ≤ 317 mm in length

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

V-PRO 1, 1 Plus, maX & maX 2 Lumen Cycle

- Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors
- Non-lumened devices including non-lumened rigid and semi-rigid endoscopes
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
  - single or dual lumen devices
    - ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm in length
  - triple lumen devices
    - ≥ 1.2 mm ID and ≤ 275 mm in length
    - ≥ 1.8 mm ID and ≤ 310 mm in length
      or
    - ≥ 2.8 mm ID and ≤ 317 mm in length

V-PRO 1, 1 Plus, maX & maX 2 Non Lumen Cycle

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

V-PRO 1, 1 Plus, maX & maX 2 Flexible Cycle

Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load.
The flexible endoscopes may contain either:

- a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
- or two lumens with:
  - one lumen that is ≥ 1 mm ID and < 990 mm in length
  - and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length

Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.

V-PRO maX 2 Fast Non Lumen Cycle

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

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.

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510(k) Summary
For K183301
PRO-LITE™ Sterilization Tray

Sponsor Facility

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Senior Regulatory Affairs Specialist

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Submission Date: November 26, 2018

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, K172755

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, V-PRO 1 Plus, V-PRO maX, V-PRO maX 2, V-PRO 60 and V-PRO s2 Low Temperature Sterilization Systems. 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 (K172755) 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 claims for the use of tray models in the V-PRO Sterilizers for:

- Qualification for use with devices having stainless steel lumens of the following configurations:
  - ≥ 2.0 mm ID and ≤ 400 mm in length
  - ≥1.0 mm ID and ≤ 254 mm in length
  - ≥ 0.76 mm ID and ≤ 233 mm in length

  in the V-PRO 60 and V-PRO s2 Sterilizer Flexible Cycle
- Qualification of use with diffusion-restricted spaces in addition to stainless steel and titanium when used in the V-PRO 60 and V-PRO s2 Sterilizer Non Lumen Cycle and Flexible Cycle.
- Qualification of use in the V-PRO s2 Sterilizer Fast Cycle
- Addition of the V-PRO s2 Sterilizer to the indications for use in the Lumen Cycle

Table 5-4: V-PRO Cycles Provided V-PRO 60 and s2 Sterilizers

Cycle	Most Recent Premarket Notification Clearance	V-PRO 60	V-PRO s2
Lumen Cycle	K172319	X	X
Non Lumen Cycle		X	X
Flexible Cycle		X	X
Fast Cycle	Concurrent Submission (K182528)		X

* Shaded cell indicates that the V-PRO Sterilizer does not include the identified cycle.

NOTE: V-PRO Sterilizer cycles are pre-set and thus the name of the cycle describes the cycle conditions.

4. Indications for Use

The PRO-LITE™ Sterilization Trays are used to contain medical devices for sterilization in the following Cycles:

- Lumen, Non Lumen, Flexible, Fast Non Lumen and Fast Cycles of the V-PRO® Low Temperature Sterilization Systems

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 & s2 Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ single or dual lumen devices ▪ ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm in length ○ triple lumen devices

Tray Models	Intended Sterilization Cycles	Intended Tray Load
		▪ ≥1.2 mm ID and ≤ 275 mm in length ▪ ≥1.8 mm ID and ≤ 310 mm in length or ▪ ≥2.8 mm ID and ≤ 317 mm in length
	V-PRO 60 & s2 Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	V-PRO 60 & s2 Flexible Cycle	Load 1: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a: o 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: o ≥ 2 mm ID and ≤ 400 mm in length o ≥ 0.76 mm ID and ≤ 233 mm in length o ≥1.0 mm ID and ≤ 254 mm in length
VP0045 VP0046 VP0047 VP0048 VP0049	V-PRO s2 Fast Cycle	• Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscope, 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 devices ▪ ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm in length o triple lumen devices ▪ ≥1.2 mm ID and ≤ 275 mm in length ▪ ≥1.8 mm ID and ≤ 310 mm in length or ▪ ≥2.8 mm ID and ≤ 317 mm in length

Tray Models	Intended Sterilization Cycles	Intended Tray Load
VP0045 VP0046 VP0047 VP0048 VP0049 VP0050 VP0051 VP0052 VP0053	V-PRO 1, 1 Plus, maX & maX 2 Lumen Cycle	• Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ single or dual lumen devices ▪ ≥ 0.77 mm ID and ≤ 527 mm in length ○ triple lumen devices ▪ ≥ 1.2 mm ID and ≤ 275 mm in length ▪ ≥ 1.8 mm ID and ≤ 310 mm in length or ▪ ≥ 2.8 mm ID and ≤ 317 mm in length
	V-PRO 1 Plus, maX & maX 2 Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.
	V-PRO maX & maX 2 Flexible Cycle	Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain either: • a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • or two lumens with: ▪ one lumen that is ≥ 1 mm ID and ≤ 990 mm in length ▪ and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors.
	V-PRO maX 2 Fast Non Lumen Cycle	Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors.

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. Technological Characteristic Comparison Table

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)	PRO-LITE Sterilization Tray (K172755)	Comparison
Intended Use	The PRO-LITE Sterilization Trays are used to contain medical devices for sterilization in the following Cycles: • Lumen, Non Lumen, Flexible, Fast Non Lumen and Fast Cycles of the V-PRO® Low Temperature Sterilization Systems 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	The PRO-LITE Sterilization Trays are used to contain medical devices for sterilization in the Lumen, Non Lumen, Flexible and Fast Non Lumen Cycles of the V-PRO Low Temperature Sterilization Systems. Prior to placing in the Sterilizer, the trays must either be: • wrapped with a legally marketed sterilization wrap for use in the V-PRO Low Temperature Sterilization Systems or • placed inside a legally marketed pouch for enclosing trays in the V-PRO Low Temperature Sterilization Systems. 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	Identical except for: • The addition of the Fast Cycle of the V-PRO s2 Sterilizer. The Fast Cycle is a new cycle in the V-PRO s2 Low Temperature Sterilizer, subject of a concurrent submission (K182568). • The extension of claims in the V-PRO 60 & s2 Sterilizers Flexible Cycle.

Feature	PRO-LITE Sterilization Tray (proposed)	PRO-LITE Sterilization Tray (K172755)	Comparison
	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 & s2 Lumen Cycle</u>: • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ○ <u>single or dual lumen devices</u> ▪ ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm in length ○ <u>triple lumen devices</u> ▪ ≥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	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 Lumen Cycle</u> • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors • Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ➢ single or dual lumen devices ≥ 0.77 mm ID and less than or equal to 410 mm in length ➢ triple lumen devices ≥1.2 mm ID and less than or equal to 275 mm in length ≥1.8 mm ID and less than or equal to 310 mm in length or ≥2.8 mm ID and less than or equal to 317 mm in length	

Feature	PRO-LITE Sterilization Tray (proposed)	PRO-LITE Sterilization Tray (K172755)	Comparison
	V-PRO 60 & s2 Non Lumen Cycle: Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with diffusion-restricted spaces such as the hinged portion of forceps and scissors. V-PRO 60 & s2 Flexible Cycle: Load 1: One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a: o 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: o ≥ 2 mm ID and ≤ 400 mm in length o ≥ 0.76 mm ID and ≤ 233 mm in length o ≥ 1.0 mm ID and ≤ 254 mm in length	V-PRO 60 Non Lumen Cycle - Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors. V-PRO 60 Flexible Cycle - One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and less than or equal 990 mm in length	

Feature	PRO-LITE Sterilization Tray (proposed)	PRO-LITE Sterilization Tray (K172755)	Comparison
	Intended Sterilization Cycles and Intended Tray Loads for Tray models: VP0045, VP0046, VP0047, VP0048, VP0049 <u>V-PRO s2 Fast Cycle:</u> • Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscope, 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: ○ <u>single or dual lumen devices</u> ▪ ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm in length ○ <u>triple lumen devices</u> ▪ ≥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 <u>V-PRO 1, 1 Plus, maX & maX 2 Lumen Cycle</u>: • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors	Intended Sterilization Cycles and Intended Tray Loads for Tray models: VP0045, VP0046, VP0047, VP0048, VP0049, VP0050, VP0051, VP0052, VP0053 <u>V-PRO 1, 1 Plus, maX, & maX 2 Lumen Cycle</u> • Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors	

Feature	PRO-LITE Sterilization Tray (proposed)	PRO-LITE Sterilization Tray (K172755)	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: ○ <u>single or dual lumen devices</u> ▪ ≥ 0.77 mm ID and ≤ 527 mm in length ○ <u>triple lumen devices</u> ▪ ≥ 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 <u>V-PRO 1, 1 Plus, maX & maX 2 Non Lumen Cycle</u>: Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors. <u>V-PRO 1, 1 Plus, maX & maX 2 Flexible Cycle</u>: <u>Load 1:</u> 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.	• Non-lumened devices including non-lumened rigid and semi-rigid endoscopes • Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations: ➢ single or dual lumen devices ≥ 0.77 mm ID and less than or equal to 527 mm in length ➢ triple lumen devices ≥1.2 mm ID and less than or equal to 275 mm in length ≥1.8 mm ID and less than or equal to 310 mm in length or ≥2.8 mm ID and less than or equal to 317 mm in length <u>V-PRO 1 Plus, maX, & maX 2 Non Lumen Cycle</u> - Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors. <u>V-PRO maX & maX 2 Flexible Cycle</u> Load 1: Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes with a light cord (if not integral to endoscope) and mat with no additional load.	

Feature	PRO-LITE Sterilization Tray (proposed)	PRO-LITE Sterilization Tray (K172755)	Comparison
	The flexible endoscopes may contain either: • a single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length • or two lumens with: ▪ one lumen that is ≥ 1 mm ID and ≤ 990 mm in length ▪ and the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors. V-PRO maX 2 Fast Non Lumen Cycle: Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors. Instrument organizers are optional accessories intended to stabilize cylindrical medical instruments with in the Sterilization Trays. Sterilization mats are optional accessories intended to cushion and stabilize instruments within the Sterilization Trays.	The flexible endoscopes may contain either: a single lumen that is ≥ 1 mm ID and less than or equal 1050 mm in length or two lumens with: one lumen that is ≥ 1 mm ID and less than or equal 990 mm in length and the other lumen that is ≥ 1 mm ID and less than or equal 850 mm in length Load 2: Non-lumened instruments including instruments with diffusion-restricted areas such as the hinged portion of forceps or scissors. V-PRO maX 2 Fast Non Lumen Non-lumened devices including non-lumened rigids, semi-rigids and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors. Instrument organizers are optional accessories intended to stabilize cylindrical medical instruments within the PRO-LITE Sterilization Trays. Sterilization mats are optional accessories intended to cushion and stabilize instruments within the PRO-LITE Sterilization Trays.	
Vent to Volume Ratio	All trays are the same: 0.135 in^{-1}	All trays are the same: 0.135 in^{-1}	Identical.
Tray Composition	Mineral-filled polypropylene, stainless steel	Mineral-filled polypropylene, stainless steel	Identical.

Feature	PRO-LITE Sterilization Tray (proposed)	PRO-LITE Sterilization Tray (K172755)	Comparison
Instrument Organizer Composition	Medical Grade Silicone, USP grade VI	Medical Grade Silicone, USP grade VI	Identical.
Mat Composition	Medical Grade Silicone, USP grade VI	Medical Grade Silicone, USP grade VI	Identical.

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		Acceptance Criteria	Conclusion
Demonstration of Effective Sterilant Penetration	V-PRO s2 Sterilizer Fast Cycle	Worst case stainless steel lumen test articles shall be reproducibly sterilized under worst case ½ cycle conditions for the Fast Cycle	PASS
		Diffusion-restricted spaces shall be reproducibly sterilized under worst case ½ cycle conditions for the Fast Cycle	PASS
		Contact points between medical devices and tray accessories shall be reproducibly sterilized under worst case ½ cycle conditions for the Fast Cycle	PASS
		Worst case surface sterilization test articles shall be reproducibly sterilized under worst case ½ cycle conditions for the Fast cycle	PASS
	V-PRO 60 & s2 Sterilizer Non Lumen Cycle, diffusion-restricted spaces claims	Diffusion-restricted spaces shall be reproducibly sterilized under worst case ½ cycle conditions for the Non Lumen Cycle	PASS
	V-PRO 60 & s2 Sterilizer Flexible Cycle, diffusion-restricted spaces claims	Diffusion-restricted spaces shall be reproducibly sterilized under worst case ½ cycle conditions for the Flexible Cycle	PASS
	V-PRO 60 & s2 Sterilizer Flexible Cycle Extended Claims	Stainless steel test articles shall be reproducibly sterilized under worst case ½ cycle conditions for the Flexible Cycle	PASS

Package Integrity	Not applicable. The Sterilization Tray meets the definition of a "tray" in ANSI/AAMI ST77:2013, *Containment devices for reusable medical device sterilization*, therefore package integrity and maintenance of package integrity testing are not applicable	
Maintenance of Package Integrity		
Demonstration of Effective Drying and Aeration	Residual hydrogen peroxide levels shall be below acceptable levels after exposure to worst case Sterilizer Cycle conditions	PASS
Demonstration of Material Compatibility	After processing through multiple worst case sterilization cycles, the trays and accessories shall retain functionality	PASS
Demonstration of Biocompatibility	Component materials shall be non-cytotoxic after exposure to worst case Sterilizer Conditions	PASS
Demonstration of Effective Cleaning	Sterilization Trays and accessories must be clean following automated and manual cleaning	PASS

7. Conclusion

Based on the intended use, technological characteristics and non-clinical performance data, the subject device is as safe, as effective and performs as well as or better than the legally marketed predicate device (K172755), Class II (21 CFR 880.6850), product code KCT.