October 7, 2024

PRIMED Medical Products Inc.
Mitra Fard
Manager, Regulatory Affairs
200, 2003 91 St SW
Edmonton, AB T6X0W8
Canada

Re: K242208
Trade/Device Name: PRIMED Sterilization Wrap (P100, P200, P300, P400, P500, P600)
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: July 25, 2024
Received: July 29, 2024

Dear Mitra Fard:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen A. Anisko -S

Digitally signed by Stephen A. Anisko -S
Date: 2024.10.07 11:34:31 -04'00'

for: Christopher Dugard
Assistant Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and
Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242208

Device Name
PRIMED Sterilization Wrap (P100, P200, P300, P400, P500, P600)

Indications for Use *(Describe)*

The PRIMED Sterilization wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider via the following:

- Pre-Vacuum Steam at 270°F/ 132°C for 4 minutes. The wrap has been validated for dry time of 20 minutes for P100 and P200 and dry time of 30 minutes for P300, P400, P500 and P600.
- 100% Ethylene Oxide Sterilization with a concentration of 725-735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes. Validated for aeration times of 8 hours at 55°C or 12 hours at 43.3°C.
- Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO maX/maX2 and STERIS V-PRO 60/s2 low temperature Sterilization Systems.
- Advanced Sterilization Products STERRAD 100S system
- Advanced Sterilization Products STERRAD NX [Standard Cycle, Advanced Cycle]
- Advanced Sterilization Products STERRAD 100 NX [Standard Cycle, Flex Cycle, Express, Duo Cycle]

PRIMED Sterilization wraps are available in 6 models and different sizes ranging from 12" X 12" to 54" X 90" and are intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) for a maximum of 180 days or until used. PRIMED Sterilization wraps are validated for use with above listed sterilization systems with the intended loads as described below.

Model	Intended Load	Maximum Recommended Wrapped Package Content		
		Pre-Vacuum Steam and EO	ASP STERRAD 100S, 100NX and NX	STERIS V-PRO
P100	Very light weight package. For example, light handle covers or towel packs.	3 lbs	3 lbs	3 lbs
P200	Light weight package. For example, standard linen packs	6 lbs	6 lbs	6.5 lbs
P300	Light to moderate weight package. For example, general use medical instruments.	9 lbs	9 lbs	9 lbs
P400	Moderate to heavy weight package. For example, general use medical instruments.	13 lbs	10.7 lbs	12 lbs
P500	Heavy weight package. For example, general use medical instruments	17 lbs	10.7 lbs	12 lbs
P600	Very heavy weight package. For example, general use medical instruments.	25 lbs	10.7 lbs	12 lbs

PRIMED wraps are validated for Pre-Vacuum Steam and EO sterilization with two 3.0mm x 400 mm lumen devices as part of the load.
PRIMED wraps are validated for ASP STERRAD 100 S sterilization with 10 stainless steel lumens (2mm ID x 250 mm length) as part of their load.
PRIMED Sterilization wraps are validated for use with STERIS V-PRO cycles and intended load as listed below:

V-PRO 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/maX2 Lumen Cycle:

- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Single, dual, or triple channeled stainless steel lumen 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 .
- Dead end lumen that is ≥ 1.3 mm ID and ≤ 73 mm in length
- Rigid non-metallic lumen that are:
  - o ≥ 3 mm ID and ≤ 298 mm in length.
  - o ≥ 4 mm ID and ≤ 424 mm in length.

V-PRO maX/maX2 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 configurations:
  - o Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain:
    - Single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length
  - o One flexible endoscope with a light cord (if not integral to the endoscope) and mat and additional instruments. The flexible endoscope may contain:
    - Single or dual channel lumens that are ≥ 1 mm ID and ≤ 1050 mm in length
    - Additional load, up to 24 lbs (11 kg) can include lumened or non-lumened medical devices:
      - Single, dual, or triple channel stainless steel lumens ≥0.48 mm ID and ≤ 100 mm in length

V-PRO 60/s2 Non-Lumen Cycle:

- Non-lumened instruments and 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 60/s2 Lumen Cycle:

- Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Medical devices (including single, dual, and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
  - o Single or dual channeled 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 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/s2 Flexible Cycle:

- Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- One surgical flexible endoscope (such as those used in ENT, Urology and Surgical Care) or bronchoscope with light cord (if not integral to the endoscope), mat, and additional load.
  - o The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length.
  - o Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions:
    - ≥ 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

The PRIMED Sterilization wraps are validated with ASP STERRAD 100 NX and ASP STERRAD NX and ASP STERRAD 100s sterilization cycles and intended load detailed below:

STERRAD 100NX Standard cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter. (A maximum of ten single channel stainless steel lumens, five per tray per sterilization cycle).

STERRAD 100NX Flex Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including most flexible endoscopes, with the following materials and dimensions:
  - o Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of 1065 mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load)

STERRAD 100NX Express Cycle:

- Instruments surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including rigid or semi-rigid endoscopes without lumen.

STERRAD 100NX DUO Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including most flexible endoscopes, with the following materials and dimensions:
  - o Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and a length of 875 mm or shorter
  - o Accessory devices that are normally connected to a flexible endoscope during use.
  - o Flexible endoscopes without lumens

STERRAD NX Standard cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors and up to 10 lumens of followings.
  - o Single channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 150 mm or shorter
  - o Single-channel stainless steel lumens with an inside diameter of 2 mm or larger and a length of 400 mm or shorter

STERRAD NX Advanced Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Single channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 500 mm or shorter (up to 10 Lumen per load)
- Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscope with an inside diameter of 1 mm or larger and length of 1065 mm or shorter (no additional load)

STERRAD 100s:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Metal and nonmetal lumened instruments with inside diameter of 6 mm or larger and length of 310 mm or shorter.
- A single stainless steel lumen with an inside diameter of 3 mm or larger and a length of 400 mm or shorter.

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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Summary Date:	July 25, 2024
Manufacturer:	PRIMED Medical Products Inc.
Address:	200, 2003-91 St. SW, Edmonton, AB, Canada, T6X 0W8
Phone Number	+1.877.877.4633
Fax Number	+1.780.497.7670
Email	mitra.fard@primed.com
Contact person:	Mitra Fard
Common name of the device	Sterilization Wrap
Trade or Proprietary Name:	PRIMED Sterilization Wrap
Models	P100, P200, P300, P400, P500, P600
Regulation Description	Sterilization Wrap
Review Panel	General Hospital
Regulation number	21 CFR 880.6850
Device Class:	Class II
Product Code:	FRG
Predicate device(s)	PRIMED Sterilization Wrap K233777

Device Description:

The PRIMED Sterilization wraps are made of SMS (Spunbond Meltblown Spunbond) Polypropylene with addition of a master batch pigment for coloration and are available in three separate product offerings:

1- The Fused one colour double layer bonded wrap is comprised of two sheets ultrasonically bonded on two parallel sides. The wrap fabrics are composed of polypropylene with the addition of purple pigment. This product allows convenient simultaneous wrapping of medical devices to be sterilized in accordance with standard healthcare practices.

2- The Fused two colours double layer bonded wrap is comprised of two sheets of purple and blue fabrics ultrasonically bonded on two parallel sides. The wrap fabrics are composed of polypropylene with the addition of purple or blue pigment. This product allows convenient simultaneous wrapping of medical devices to be sterilized in accordance with standard healthcare practices.

3- The Single layer one colour wrap is comprised of a single nonwoven sheet. The standard purple wrap is composed of polypropylene with the addition of a purple pigment. Two sheets are used to sequentially wrap medical devices to be sterilized in accordance with standard healthcare practices.

PRIMED Sterilization wraps are available in various dimensions ranging from 12” x 12” to 54” x 90” and six different weights as detailed in table 1.

Table 1: Wrap types and size

Model	P100 (40 gsm)			P200 (45 gsm)			P300 (50 gsm)			P400 (65 gsm)			P500 (72 gsm)			P600 (88 gsm)		
Type / Size	F1	F2	S	F1	F2	S	F1	F2	S	F1	F2	S	F1	F2	S	F1	F2	S
12” X 12”	✓	✓	✓	✓	✓	✓												
15” X 15”	✓	✓	✓			✓												
18” X 18”	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
20” X 20”	✓	✓	✓															
24” X 24”	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓			
30” X 30”	✓	✓	✓		✓	✓	✓	✓	✓			✓	✓	✓	✓			
36” X 36”	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
40” X 40”	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓				✓	✓	✓
45” X 45”	✓	✓	✓				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
48” X 48”	✓	✓	✓			✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
54” X 54”	✓	✓	✓				✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
60” X 60”														✓				
54” X 72”			✓			✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓
54” X 90”	✓	✓					✓	✓					✓	✓		✓	✓	

F1: Fused 1 color double layer wrap,
F2: Fused 2 color double layer wrap and
S: Single layer wrap

Indication for Use

The PRIMED Sterilization wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider via the following:

- Pre-Vacuum Steam at 270°F/ 132°C for 4 minutes. The wrap has been validated for dry time of 20 minutes for P100 and P200 and dry time of 30 minutes for P300, P400, P500 and P600.
- 100% Ethylene Oxide Sterilization with a concentration of 725-735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes. Validated for aeration times of 8 hours at 55°C or 12 hours at 43.3°C.
- Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO maX/maX2 and STERIS V-PRO 60/s2 low temperature Sterilization Systems.
- Advanced Sterilization Products STERRAD 100S system
- Advanced Sterilization Products STERRAD NX [Standard Cycle, Advanced Cycle]
- Advanced Sterilization Products STERRAD 100 NX [Standard Cycle, Flex Cycle, Express, Duo Cycle]

PRIMED Sterilization wraps are available in 6 models and different sizes ranging from 12" X 12" to 54" X 90" and are intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) for a maximum of 180 days or until used.
PRIMED Sterilization wraps are validated for use with above listed sterilization systems with the intended loads as described below.

Table 2: Maximum recommended wrapped package content:

Model	Intended Load	Maximum Recommended Wrapped Package Content		
		Pre-Vacuum Steam and EO	ASP STERRAD 100S, 100NX and NX	STERIS V-PRO
P100	Very light weight package. For example, light handle covers or towel packs.	3 lbs	3 lbs	3 lbs
P200	Light weight package. For example, standard linen packs	6 lbs	6 lbs	6.5 lbs
P300	Light to moderate weight package. For example, general use medical instruments.	9 lbs	9 lbs	9 lbs
P400	Moderate to heavy weight package. For example, general use medical instruments.	13 lbs	10.7 lbs	12 lbs
P500	Heavy weight package. For example, general use medical instruments	17 lbs	10.7 lbs	12 lbs
P600	Very heavy weight package. For example, general use medical instruments.	25 lbs	10.7 lbs	12 lbs

PRIMED wraps are validated for Pre-Vacuum Steam and EO sterilization with two 3.0mm x 400 mm lumen devices as part of the load.

PRIMED wraps are validated for ASP STERRAD 100 S sterilization with 10 stainless steel lumens (2mm ID x 250 mm length) as part of their load.

PRIMED Sterilization wraps are validated for use with STERIS V-PRO cycles and intended load as listed below:

V-PRO 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/maX2 Lumen Cycle:

- Non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Single, dual, or triple channelled stainless-steel lumen that are:
  - $\geqslant$ 0.77 mm ID and $\leqslant$ 527 mm in length.
  - $\geqslant$ 0.8 mm ID and $\leqslant$ 542 mm in length.
  - $\geqslant$0.48 mm ID and $\leqslant$ 100 mm in length .
- Dead end lumen that is $\geqslant$ 1.3 mm ID and $\leqslant$ 73 mm in length
- Rigid non-metallic lumen that are:
  - $\geqslant$ 3 mm ID and $\leqslant$ 298 mm in length.
  - $\geqslant$ 4 mm ID and $\leqslant$ 424 mm in length.

V-PRO maX/maX2 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 configurations:

- Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load. The flexible endoscopes may contain:
  - Single or dual channel lumens that are ⩾ 1 mm ID and ⩽ 1050 mm in length
- One flexible endoscope with a light cord (if not integral to the endoscope) and mat and additional instruments. The flexible endoscope may contain:
  - Single or dual channel lumens that are ⩾ 1 mm ID and ⩽ 1050 mm in length
  - Additional load, up to 24 lbs (11 kg) can include lumened or non-lumened medical devices:
    - Single, dual, or triple channel stainless steel lumens ⩾0.48 mm ID and ⩽ 100 mm in length

V-PRO 60/s2 Non-Lumen Cycle:

- Non-lumened instruments and 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 60/s2 Lumen Cycle:

- Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- Medical devices (including single, dual, and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
  - Single or dual channeled devices with stainless steel lumens that are:
    - ⩾ 0.77 mm ID and ⩽ 410 mm in length.
    - ⩾ 1.8 mm ID and ⩽ 542 mm in length.
  - Triple channeled devices with stainless steel lumens that are either:
    - ⩾1.2 mm ID and ⩽275 mm in length
    - ⩾1.8 mm ID and ⩽ 310 mm in length or
    - ⩾ 2.8 mm ID and ⩽317 mm in length

V-PRO 60/s2 Flexible Cycle:

- Non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.
- One surgical flexible endoscope (such as those used in ENT, Urology and Surgical Care) or bronchoscope with light cord (if not integral to the endoscope), mat, and 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.
  - Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions:
    - ⩾ 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

The PRIMED Sterilization wraps are validated with ASP STERRAD 100 NX and ASP STERRAD NX and ASP STERRAD 100s sterilization cycles and intended load detailed below:

STERRAD 100NX Standard cycle:

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

- Single channel stainless steel lumens with an inside diameter of 0.7 mm or larger and a length of 500 mm or shorter. (A maximum of ten single channel stainless steel lumens, five per tray per sterilization cycle).

STERRAD 100NX Flex Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including most flexible endoscopes, with the following materials and dimensions:
  - Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and length of 1065 mm or shorter. (A maximum of two flexible endoscopes, one per tray per sterilization cycle. No additional load)

STERRAD 100NX Express Cycle:

- Instruments surfaces and instruments having diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including rigid or semi-rigid endoscopes without lumen.

STERRAD 100NX DUO Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Medical devices, including most flexible endoscopes, with the following materials and dimensions:
  - Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscopes with an inside diameter of 1 mm or larger and a length of 875 mm or shorter
  - Accessory devices that are normally connected to a flexible endoscope during use.
  - Flexible endoscopes without lumens

STERRAD NX Standard cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors and up to 10 lumens of followings.
  - Single channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 150 mm or shorter
  - Single-channel stainless steel lumens with an inside diameter of 2 mm or larger and a length of 400 mm or shorter

STERRAD NX Advanced Cycle:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Single channel stainless steel lumens with an inside diameter of 1 mm or larger and a length of 500 mm or shorter (up to 10 Lumen per load)
- Single channel polyethylene and Teflon (polytetrafluoroethylene) flexible endoscope with an inside diameter of 1 mm or larger and length of 1065 mm or shorter (no additional load)

STERRAD 100s:

- Instruments with diffusion-restricted spaces, such as the hinged portion of forceps and scissors.
- Metal and nonmetal lumened instruments with inside diameter of 6 mm or larger and length of 310 mm or shorter.
- A single stainless steel lumen with an inside diameter of 3 mm or larger and a length of 400 mm or shorter.

Here below is the summary of the technological characteristics and performance of the proposed device compared to the predicate device.

Table 3: Comparison of Technological Characteristics with Predicate Device

Elements of Comparison	Proposed device PRIMED Sterilization wraps (K242208)	Predicate device PRIMED Sterilization wraps (K233777)	Comparison to Predicate
Manufacturer	PRIMED Medical Products Inc.	PRIMED Medical Products Inc.	Similar
Regulation number	21 CFR 880.6850	21 CFR 880.6850	Similar
Product Code	FRG	FRG	Similar
Common name	Sterilization Wrap	Sterilization Wrap	Similar
Models/ Dimensions	Six basis weights and fourteen sizes	Six basis weights and fourteen sizes	Similar
Intended Use	The PRIMED Sterilization wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider via the following: - Pre-Vacuum Steam at 270°F/ 132°C for 4 minutes. The wrap has been validated for dry time of 20 minutes for P100 and P200 and dry time of 30 minutes for P300, P400, P500 and P600. - 100% Ethylene Oxide Sterilization with a concentration of 725-735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes. Validated for aeration times of 8 hours at 55°C or 12 hours at 43.3°C. - Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO maX/maX2 and STERIS V-PRO 60/s2 low temperature Sterilization Systems. - Advanced Sterilization Products STERRAD 100S system - Advanced Sterilization Products STERRAD NX [Standard Cycle, Advanced Cycle] - Advanced Sterilization Products STERRAD 100 NX [Standard Cycle, Flex Cycle, Express, Duo Cycle] PRIMED Sterilization wraps are available in 6 models and different sizes ranging from 12" X 12" to 54" X 90" and are intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.	The PRIMED Sterilization wraps are intended to be used to enclose another medical device that is to be sterilized by a health care provider via the following: - Pre-Vacuum Steam at 270°F/ 132°C for 4 minutes. The wrap has been validated for dry time of 20 minutes for P100 and P200 and dry time of 30 minutes for P300, P400, P500 and P600. - 100% Ethylene Oxide Sterilization with a concentration of 725-735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes. Validated for aeration times of 8 hours at 55°C or 12 hours at 43.3°C. - Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO maX/maX2 and STERIS V-PRO 60/s2 low temperature Sterilization Systems. - Advanced Sterilization Products STERRAD 100S system - Advanced Sterilization Products STERRAD NX [Standard Cycle, Advanced Cycle] - Advanced Sterilization Products STERRAD 100 NX [Standard Cycle, Flex Cycle, Express, Duo Cycle] PRIMED Sterilization wraps are available in 6 models and different sizes ranging from 12" X 12" to 54" X 90" and are intended to allow sterilization of the enclosed medical device(s) and maintain sterility of the enclosed device(s) until used.	Similar
Prescription vs. OTC	OTC	OTC	Similar
Single use vs. reusable	Single Use Only	Single Use Only	Similar
Material Composition	PRIMED wraps are composed of Spunbond Meltblown Sponbund material	PRIMED wraps are composed of Spunbond Meltblown Sponbund material	Similar
Chemical Properties	Polypropylene with blue pigment and antistatic treatment	Polypropylene with blue pigment and antistatic treatment Polypropylene with purple pigment and antistatic treatment	Similar

<table>
<tr><th>Elements of Comparison</th><th>Proposed device
PRIMED Sterilization wraps (K242208)</th><th>Predicate device
PRIMED Sterilization wraps (K233777)</th><th>Comparison to Predicate</th></tr>
<tr><td></td><td>Polypropylene with purple pigment and antistatic treatment</td><td></td><td></td></tr>
<tr><td>Device Design</td><td>- The Fused one colour double layer bonded wrap is comprised of two sheets ultrasonically bonded on two parallel sides. The wrap fabrics are composed of polypropylene with the addition of purple pigment.
- The Fused two colours double layer bonded wrap is comprised of two sheets of purple and blue fabrics ultrasonically bonded on two parallel sides. The wrap fabrics are composed of polypropylene with the addition of purple or blue pigment.
- The Single layer one colour wrap is comprised of a single nonwoven sheet. The standard purple wrap is composed of polypropylene with the addition of a purple pigment.</td><td>- The Fused one colour double layer bonded wrap is comprised of two sheets ultrasonically bonded on two parallel sides. The wrap fabrics are composed of polypropylene with the addition of purple pigment.
- The Fused two colours double layer bonded wrap is comprised of two sheets of purple and blue fabrics ultrasonically bonded on two parallel sides. The wrap fabrics are composed of polypropylene with the addition of purple or blue pigment.
- The Single layer one colour wrap is comprised of a single nonwoven sheet. The standard purple wrap is composed of polypropylene with the addition of a purple pigment.</td><td>Similar</td></tr>
<tr><td>Sterilization Parameter</td><td>- Pre-vacuum steam at 270°F/132°C for 4 minutes.
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/l at 131°F/55°C and 40%-80% relative humidity for 60 minutes.
- STERRAD® 100S short and long cycle.
- STERRAD® NX, Standard and Advanced Cycles.
- STERRAD® 100NX, Standard, Flex, Express and Duo Cycles.
- Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO maX/maX2, V-PRO 60/s2 Low Temperature sterilization system.</td><td>- Pre-vacuum steam at 270°F/132°C for 4 minutes.
- 100% ethylene oxide (EO) with a concentration of 725-735 mg/l at 131°F/55°C and 40%-80% relative humidity for 60 minutes.
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<tr><td>Maximum Wrapped package content weight</td><td><table><tr><th>Model</th><th>Pre-Vacuum Steam and EO</th><th>ASP STERRAD 100S, 100NX and NX</th><th>STERIS V-PRO</th></tr><tr><td>P100</td><td>3 lbs</td><td>3 lbs</td><td>3 lbs</td></tr><tr><td>P200</td><td>6 lbs</td><td>6 lbs</td><td>6.5 lbs</td></tr><tr><td>P300</td><td>9 lbs</td><td>9 lbs</td><td>9 lbs</td></tr><tr><td>P400</td><td>13 lbs</td><td>10.7 lbs</td><td>12 lbs</td></tr><tr><td>P500</td><td>17 lbs</td><td>10.7 lbs</td><td>12 lbs</td></tr><tr><td>P600</td><td>25 lbs</td><td>10.7 lbs</td><td>12 lbs</td></tr></table></td><td><table><tr><th>Model</th><th>Pre-Vacuum Steam and EO</th><th>ASP STERRAD 100S, 100NX and NX</th><th>STERIS V-PRO</th></tr><tr><td>P100</td><td>3 lbs</td><td>3 lbs</td><td>3 lbs</td></tr><tr><td>P200</td><td>6 lbs</td><td>6 lbs</td><td>6.5 lbs</td></tr><tr><td>P300</td><td>9 lbs</td><td>9 lbs</td><td>9 lbs</td></tr><tr><td>P400</td><td>13 lbs</td><td>10.7 lbs</td><td>12 lbs</td></tr><tr><td>P500</td><td>17 lbs</td><td>10.7 lbs</td><td>12 lbs</td></tr><tr><td>P600</td><td>25 lbs</td><td>10.7 lbs</td><td>12 lbs</td></tr></table></td><td>Similar</td></tr>
<tr><td>Maintenance of Package Integrity</td><td>180 days</td><td>30 days</td><td>Different (Note)</td></tr>
<tr><td>Sterilant Penetration and Efficacy</td><td>Negative for growth</td><td>Negative for growth</td><td>Similar</td></tr>
<tr><td>Maintenance of package sterility</td><td>Microbial Aerosol Challenge test, Negative for growth</td><td>Microbial Aerosol Challenge test, Negative for growth</td><td>Similar</td></tr>
</table>

Elements of Comparison	Proposed device PRIMED Sterilization wraps (K242208)	Predicate device PRIMED Sterilization wraps (K233777)	Comparison to Predicate
Maintenance of package Integrity	No growth	No growth	Similar
Biocompatibility	PRIMED wraps are tested for Cytotoxicity, Irritation and sensitization and are considered non-cytotoxic, non-irritating and non-sensitizing	PRIMED wraps are tested for Cytotoxicity, Irritation and sensitization and are considered non-cytotoxic, non-irritating and non-sensitizing	Similar
Leachability	Extract prepared as per ISO 6588-2 is colourless, its PH, chloride content, sulphate content meets the requirement of EN 868-2	Extract prepared as per ISO 6588-2 is colourless, its PH, chloride content, sulphate content meets the requirement of EN 868-2	Similar
Residuals, ISO 10993- 7	None detected	None detected	Similar
Physical and chemical properties comparison	Compatible with the requirements of Basis weight, Air permeability, Material burst strength, Grab Tensile strength, Trapezoidal Tear strength, Hydrostatic Pressure and linting	Compatible with the requirements of Basis weight, Air permeability, Material burst strength, Grab Tensile strength, Trapezoidal Tear strength, Hydrostatic Pressure and linting	Similar

Note: Testing reports demonstrate that the PRIMED Sterilization wraps can maintain the sterility of the enclosed medical device for 180 days and are safe and effective for their intended use.

Overall Performance Conclusions:

PRIMED Sterilization wraps have been tested for sterilization efficacy, event related maintenance of package integrity, physical properties, and biocompatibility. Testing results demonstrate that the PRIMED Sterilization Wraps allow sterilization of the enclosed medical device and maintain the sterility of the content for 180 days post sterilization after being sterilized with one of following sterilization cycles:

- Pre-Vacuum Steam at 270°F/ 132°C for 4 minutes.
- 100% Ethylene Oxide Sterilization with a concentration of 725-735 mg/L at 131°F/55°C and 40% - 80% relative humidity for 60 minutes.
- Lumen, Non-Lumen, and Flexible Cycles in the STERIS V-PRO maX/maX2 and STERIS V-PRO 60/s2 low temperature Sterilization Systems.
- Advanced Sterilization Products STERRAD 100S system
- Advanced Sterilization Products STERRAD NX [Standard Cycle, Advanced Cycle]
- Advanced Sterilization Products STERRAD 100 NX [Standard Cycle, Flex Cycle, Express, Duo Cycle]

The proposed and predicate device in this submission have the same intended use, design, material composition. And they all comply with the applicable requirements. The difference in the maintenance of package integrity as demonstrated by the completed tests, do not affect the safety and performance of the proposed device.

Table 4: Summary of the non-clinical testing:

Test Performed	Test Method	Acceptance Criteria	Results (Pass/Fail)
Sterilant Penetration	ANSI/AAMI ST79 , ANSI/AAMI/ISO 11138-7	All BI test samples should be negative for growth following the minimum incubation period	Pass
Maintenance of Package Integrity	ANSI/AAMI/ISO 11607-1, AAMI TIR12ANSI, AAMI ST79	Maintain sterility for 180 days	Pass
Maintenance of package sterility	AAMI TIR12 -ANSI/AAMI ST77	No growth in any of the culture vessels containing test coupons after the minimum incubation period	Pass
Residual	ISO 10993-7	Less than maximum theoretical residual limits or the tolerable contact limit following a 100% ethylene oxide sterilization process	Pass
Biocompatibility	Cytotoxicity, Irritation and Sensitization ISO 10993-5 and ISO 10993-10	non-cytotoxic, non-irritating and non-sensitizing	Pass
Physical and Chemical Properties and Material compatibility with the intended sterilization method, PH value, chloride content, sulphate content, colour fastness, Basis weight, Air permeability, Material burst strength, Grab Tensile strength, Trapezoidal Tear strength, Hydrostatic Pressure, Linting.	ISO 11607-1 and EN 868-2 ASTM D3776 ASTM D737-04 ASTM D3786 ASTM D5034-09 ASTM D5587-15 AATC127-2014 NWSP 160.1	Meets physical and chemical properties, non-sterile and post sterilization	Pass

Conclusion:

Based on the non-clinical testing performed, it can be concluded that the subject device, PRIMED Sterilization Wraps (P100, P200, P300, P400, P500, P600) are as safe, as effective and performs as well as or better than the legally marketed predicate device, K233777 class II (21 CFR 880.6850), PRIMED Sterilization Wrap product code FRG.