DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 18, 2016

PMS TIBBI CIHAZLAR TEKNOLOJISI SANAYI VE TICARET ANONIM ŞIRKETI
Derya Dikici, Ph.D.
Business Development Manager
Karaduvar Mahallesi, Serbest Bolge 11. Cadde No:46
Mersin Serbest Bolgesi, 33020, Akdeniz/MERSIN/TURKEY

Re: K160595
Trade/Device Name: PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG
Dated: October 10, 2016
Received: October 19, 2016

Dear Derya Dikici:

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. 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 and Part 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and Part 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160595

Device Name

PMSSteripack Tyvek Sterilization Pouch(TP) and Roll(TY) with Chemical Indicator

Indications for Use *(Describe)*

PMS Steripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator; are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in vaporized hydrogen peroxide (VHP) sterilization method.

PMS Steripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed devices until used.

The recommended (and validated) sterilization cycle parameters are:
The Steris V-PRO 1 PLUS LUMEN CYCLE is a single preprogramed standard sterilization cycle with NO cycle parameter variables allowed by the end user.

Chemical process indicator on the exterior of the Tyvek pouches and rolls indicates that the pouch has been exposed to V-PRO 1 Plus, Lumen Cycle sterilization process by changing color from red to blue or (lighter).

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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Devices with stainless steel lumens with the following internal diameter (ID) and maximum length can be processed in V-PRO 1 Plus, Lumen Cycle.

Table 1. Lumen Claims

Pouch Size	Max. lumen length	Min. internal diameter	Max # Lumens
50 x 200mm	50 mm	1.5 mm	1
150 x 300mm	3 mm	200 mm	1
350 x 600mm	3 mm	400 mm	1

Worst Case Load:

The worst case load for the 50 mm x 200 mm pouch is 0.058 lbs. of instruments.
The worst case load for the 150 mm x 300 mm pouch is 0.630 lbs. of instruments.
The worst case load for the 350 mm x 600 mm pouch is 3.054 lbs. of instruments.

K160595

510 (k) Summary
For
PMSSteripack Tyvek Sterilization Pouch(TP) and Roll (TY) with Chemical Indicator

1.0. Name, address and contact

PMS TIBBI CIHAZLAR TEKNOLOJISI SANAYI VE TICARET ANONIM ŞIRKETI
Karaduvar Mahallesi, Serbest Bolge 11. Cadde No:46
Mersin Serbest Bolgesi, 33020, Akdeniz/MERSIN/TURKEY

Phone : 90 324 2387042 – 90 542 648 6312
Fax : 90 324 2386549

Prepared by : Taner Ersen
Quality Management Representative

Contact : Derya Dikici
Business Development Manager

Phone : 90 324 2387042- 90 542 648 6312
Fax : 90 324 2386549
E-mail : derya.dikici@pmsmedikal.com

Date Prepared: **November 17, 2016**

2. Device Name

Trade Name: PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator

Common/Usual Name: Tyvek Sterilization Pouch and Roll

Device Classification Name: Wrap, Sterilization - Indicator, Physical/Chemical Sterilization Process

Product Code: FRG

Product Classification: Class II, 21 CFR 880.6850, General Hospital (FRG)

3. Predicate Device

K140487, STERIS Vis-U-All Low Temperature Sterilization Pouch/Tubing

4.Indications for use

PMS Steripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator; are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in vaporized hydrogen peroxide (VHP) sterilization method.

PMS Steripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed devices until used.

The recommended (and validated) sterilization cycle parameters are:

The Steris V-PRO 1 PLUS LUMEN CYCLE is a single preprogramed standard sterilization cycle with NO cycle parameter variables allowed by the end user.

Chemical process indicator on the exterior of the Tyvek pouches and rolls indicates that the pouch has been exposed to V-PRO 1 Plus, Lumen Cycle sterilization process by changing color from red to blue or (lighter).

Devices with stainless steel lumens with the following internal diameter (ID) and maximum length can be processed in V-PRO 1 Plus, Lumen Cycle.

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50 x 200mm	50 mm	1.5 mm	1
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Worst Case Load:

The worst case load for the 50 mm x 200 mm pouch is 0.058 lbs. of instruments.
The worst case load for the 150 mm x 300 mm pouch is 0.630 lbs. of instruments.
The worst case load for the 350 mm x 600 mm pouch is 3.054 lbs. of instruments.

5. Device Description

PMSSteripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator; are manufactured from tyvek material/laminated PET/PE film that are heat sealed on sides. Triple band seal provides three independent barriers to contamination, while reducing the risk of fibre tear.

PMSSteripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator; are divided into 2 main configuration groups as below.

Sterilization Pouches, Flat:

These pouches are manufactured from tyvek material/ laminated PET/PE plastic film that are heat sealed on 3 sides, the remaining open side is heat sealed by the end user.

Sterilization Rolls, Flat:

These rolls are manufactured from tyvek material and laminated PET/PE plastic film that are heat sealed on opposite two sides. The required size is cut from the roll and the remaining open sides are heat sealed by the end user.

Available Sizes /Configurations for TP&TY:

Table 2. Product List of "PMSSteripack Tyvek Sterilization Pouch (TP) with Chemical Indicator "

PRODUCT LIST									
Product Name	(A) Total Width (mm)	(B) Total Height (mm)	(A) Total Width (in.)	(B) Total Height (in.)	(L) Seal Width (mm)	(V) Single Seal Width (mm)	(P) Distance Between 2 Seals (mm)	(S) Diameter (mm)	(T) Thicknes (µm)
TP0520	50	200	2	8	10	2	2	10	223±18
TP0525	50	250	2	10	10	2	2	10	223±18
TP0530	50	300	2	12	10	2	2	10	223±18
TP0532	50	320	2	12¾	10	2	2	10	223±18
TP0535	50	350	2	14	10	2	2	10	223±18
TP7515	75	150	3	6	10	2	2	10	223±18
TP7518	75	180	3	7	10	2	2	10	223±18
TP7520	75	200	3	8	10	2	2	10	223±18
TP7523	75	230	3	9	10	2	2	10	223±18
TP7525	75	250	3	10	10	2	2	10	223±18
TP7528	75	280	3	11	10	2	2	10	223±18
TP7530	75	300	3	12	10	2	2	10	223±18
TP7535	75	350	3	14	10	2	2	10	223±18
TP7540	75	400	3	16	10	2	2	10	223±18

TP7545	75	450	3	18	10	2	2	10	223±18
TP0815	80	150	3¼	6	10	2	2	10	223±18
TP0817	80	170	3¼	6¾	10	2	2	10	223±18
TP0818	80	180	3¼	7	10	2	2	10	223±18
TP0820	80	200	3¼	8	10	2	2	10	223±18
TP0827	80	270	3¼	10¾	10	2	2	10	223±18
TP0860	80	600	3¼	24	10	2	2	10	223±18
TP0956	90	560	3½	22	10	2	2	10	223±18
TP0960	90	600	3½	24	10	2	2	10	223±18
TP0961	90	610	3½	24	10	2	2	10	223±18
TP1015	100	150	4	6	10	2	2	10	223±18
TP1018	100	180	4	7	10	2	2	10	223±18
TP1019	100	190	4	7½	10	2	2	10	223±18
TP1020	100	200	4	8	10	2	2	10	223±18
TP1023	100	230	4	9	10	2	2	10	223±18
TP1025	100	250	4	10	10	2	2	10	223±18
TP1026	100	260	4	10¼	10	2	2	10	223±18
TP1027	100	270	4	10¾	10	2	2	10	223±18
TP1028	100	280	4	11	10	2	2	10	223±18
TP1030	100	300	4	12	10	2	2	10	223±18
TP1033	100	330	4	13	10	2	2	10	223±18
TP1035	100	350	4	14	10	2	2	10	223±18
TP1036	100	360	4	14	10	2	2	10	223±18
TP1040	100	400	4	16	10	2	2	10	223±18
TP1045	100	450	4	18	10	2	2	10	223±18
TP1050	100	500	4	20	10	2	2	10	223±18
TP1056	100	560	4	22	10	2	2	10	223±18
TP1057	100	570	4	22	10	2	2	10	223±18
TP1060	100	600	4	24	10	2	2	10	223±18
TP1061	100	610	4	24	10	2	2	10	223±18
TP1128	110	280	4¼	11	10	2	2	10	223±18
TP1225	120	250	4¾	10	10	2	2	10	223±18
TP1230	120	300	4¾	12	10	2	2	10	223±18
TP1240	120	400	4¾	16	10	2	2	10	223±18
TP1250	120	500	4¾	20	10	2	2	10	223±18
TP1325	130	250	5	10	10	2	2	10	223±18
TP1338	130	380	5	15	10	2	2	10	223±18
TP1520	150	200	6	8	10	2	2	10	223±18
TP1525	150	250	6	10	10	2	2	10	223±18

TP1527	150	270	6	10¾	10	2	2	10	223±18
TP1528	150	280	6	11	10	2	2	10	223±18
TP1530	150	300	6	12	10	2	2	10	223±18
TP1532	150	320	6	12¾	10	2	2	10	223±18
TP1535	150	350	6	14	10	2	2	10	223±18
TP1538	150	380	6	15	10	2	2	10	223±18
TP1540	150	400	6	16	10	2	2	10	223±18
TP1543	150	430	6	17	10	2	2	10	223±18
TP1545	150	450	6	18	10	2	2	10	223±18
TP1550	150	500	6	20	10	2	2	10	223±18
TP1552	150	520	6	20¼	10	2	2	10	223±18
TP1555	150	550	6	22	10	2	2	10	223±18
TP1556	150	560	6	22	10	2	2	10	223±18
TP1640	160	400	6¼	16	10	2	2	10	223±18
TP1658	160	580	6¼	23	10	2	2	10	223±18
TP1722	170	220	6¾	8¾	10	2	2	10	223±18
TP1735	170	350	6¾	14	10	2	2	10	223±18
TP1830	180	300	7	12	10	2	2	10	223±18
TP1832	180	320	7	12¾	10	2	2	10	223±18
TP1846	180	460	7	18	10	2	2	10	223±18
TP1933	190	330	7½	13	10	2	2	10	223±18
TP2020	200	200	8	8	10	2	2	10	223±18
TP2025	200	250	8	10	10	2	2	10	223±18
TP2027	200	270	8	10¾	10	2	2	10	223±18
TP2030	200	300	8	12	10	2	2	10	223±18
TP2033	200	330	8	13	10	2	2	10	223±18
TP2035	200	350	8	14	10	2	2	10	223±18
TP2040	200	400	8	16	10	2	2	10	223±18
TP2041	200	410	8	16	10	2	2	10	223±18
TP2045	200	450	8	18	10	2	2	10	223±18
TP2050	200	500	8	20	10	2	2	10	223±18
TP2060	200	600	8	24	10	2	2	10	223±18
TP2128	210	280	8¼	11	10	2	2	10	223±18
TP2135	210	350	8¼	14	10	2	2	10	223±18
TP2140	210	400	8¼	16	10	2	2	10	223±18
TP2142	210	420	8¼	16¾	10	2	2	10	223±18
TP2228	220	280	8¾	11	10	2	2	10	223±18
TP2235	220	350	8¾	14	10	2	2	10	223±18
TP2242	220	420	8¾	16¾	10	2	2	10	223±18
TP2525	250	250	10	10	10	2	2	10	223±18

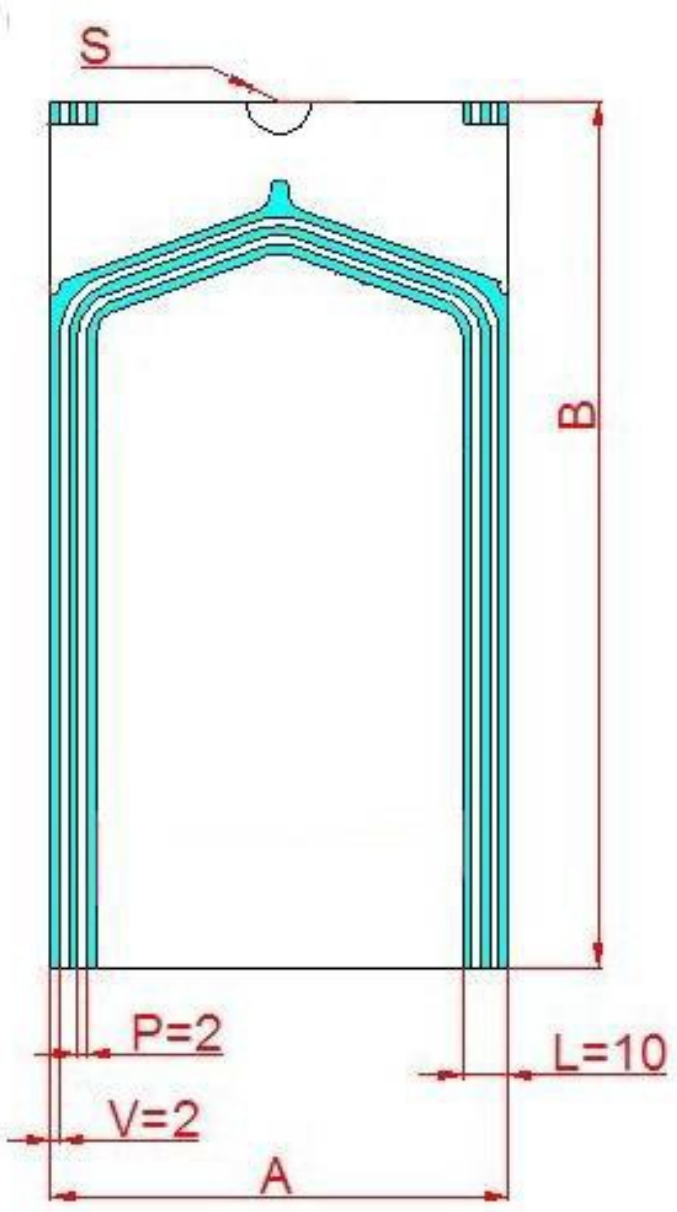
TP2530	250	300	10	12	10	2	2	10	223±18
TP2535	250	350	10	14	10	2	2	10	223±18
TP2538	250	380	10	15	10	2	2	10	223±18
TP2540	250	400	10	16	10	2	2	10	223±18
TP2545	250	450	10	18	10	2	2	10	223±18
TP2550	250	500	10	20	10	2	2	10	223±18
TP2735	270	350	10¾	14	10	2	2	10	223±18
TP2745	270	450	10¾	18	10	2	2	10	223±18
TP2835	280	350	11	14	10	2	2	10	223±18
TP2840	280	400	11	16	10	2	2	10	223±18
TP2845	280	450	11	18	10	2	2	10	223±18
TP2850	280	500	11	20	10	2	2	10	223±18
TP2857	280	570	11	22	10	2	2	10	223±18
TP3038	300	380	12	15	10	2	2	10	223±18
TP3040	300	400	12	16	10	2	2	10	223±18
TP3042	300	420	12	16¾	10	2	2	10	223±18
TP3045	300	450	12	18	10	2	2	10	223±18
TP3046	300	460	12	18	10	2	2	10	223±18
TP3050	300	500	12	20	10	2	2	10	223±18
TP3055	300	550	12	22	10	2	2	10	223±18
TP3060	300	600	12	24	10	2	2	10	223±18
TP3245	320	450	12¾	18	10	2	2	10	223±18
TP3250	320	500	12¾	20	10	2	2	10	223±18
TP3255	320	550	12¾	22	10	2	2	10	223±18
TP3346	330	460	13	18	10	2	2	10	223±18
TP3540	350	400	14	16	10	2	2	10	223±18
TP3545	350	450	14	18	10	2	2	10	223±18
TP3550	350	500	14	20	10	2	2	10	223±18
TP3552	350	520	14	20¼	10	2	2	10	223±18
TP3555	350	550	14	22	10	2	2	10	223±18
TP3560	350	600	14	24	10	2	2	10	223±18

Table 3. Product List of "PMSSteripack Tyvek Sterilization Rolls (TY) with Chemical Indicator"

PRODUCT LIST								
Product Name	**(A) Total Width (cm)**	**(B) Total Length (m)**	**(A) Total Width (in)**	**(B) Total Length (ft)**	**(L) Seal Width (mm)**	**(V) Single Seal Width**	**(P) Distance Between 2 Seals (mm)**	**(T) Thickness (µm)**
TY 0523	5	23	2	75	10	2	2	223±18
TY 7523	7.5	23	3	75	10	2	2	223±18
TY 1023	10	23	4	75	10	2	2	223±18
TY 12523	12.5	23	5	75	10	2	2	223±18
TY 1523	15	23	6	75	10	2	2	223±18
TY 2023	20	23	8	75	10	2	2	223±18
TY 2323	23	23	9	75	10	2	2	223±18
TY 2523	25	23	10	75	10	2	2	223±18
TY 3023	30	23	12	75	10	2	2	223±18
TY 3523	35	23	14	75	10	2	2	223±18
TY 3823	38	23	15	75	10	2	2	223±18
TY 4023	40	23	16	75	10	2	2	223±18
TY 4523	45	23	18	75	10	2	2	223±18
TY 5023	50	23	20	75	10	2	2	223±18
TY 0530	5	30	2	100	10	2	2	223±18
TY 7530	7.5	30	3	100	10	2	2	223±18
TY 1030	10	30	4	100	10	2	2	223±18
TY 12530	12.5	30	5	100	10	2	2	223±18
TY 1530	15	30	6	100	10	2	2	223±18
TY 2030	20	30	8	100	10	2	2	223±18
TY 2330	23	30	9	100	10	2	2	223±18
TY 2530	25	30	10	100	10	2	2	223±18
TY 3030	30	30	12	100	10	2	2	223±18
TY 3530	35	30	14	100	10	2	2	223±18
TY 3830	38	30	15	100	10	2	2	223±18
TY 4030	40	30	16	100	10	2	2	223±18
TY 4530	45	30	18	100	10	2	2	223±18
TY 5030	50	30	20	100	10	2	2	223±18
TY 0570	5	70	2	230	10	2	2	223±18
TY 7570	7.5	70	3	230	10	2	2	223±18
TY 1070	10	70	4	230	10	2	2	223±18
TY 1270	12	70	5	230	10	2	2	223±18
TY 1570	15	70	6	230	10	2	2	223±18
TY 2070	20	70	8	230	10	2	2	223±18
TY 2570	25	70	10	230	10	2	2	223±18
TY 3070	30	70	12	230	10	2	2	223±18

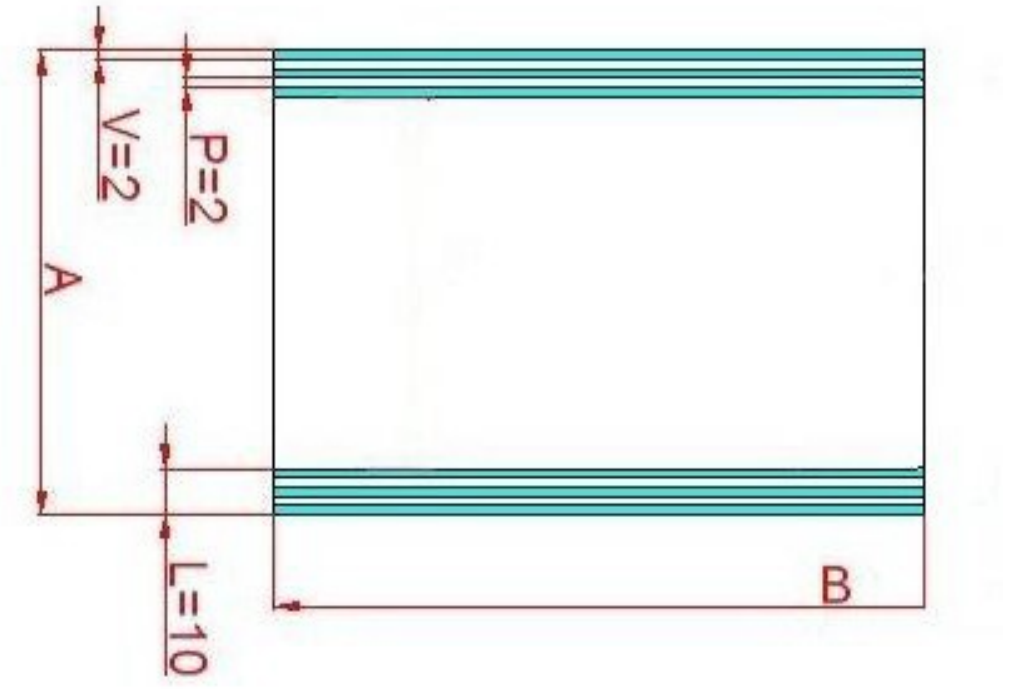
TY 3570	35	70	14	230	10	2	2	223±18
TY 4070	40	70	16	230	10	2	2	223±18
TY 4570	45	70	18	230	10	2	2	223±18
TY 5070	50	70	20	230	10	2	2	223±18
TY 05100	5	100	2	330	10	2	2	223±18
TY 75100	7.5	100	3	330	10	2	2	223±18
TY 10100	10	100	4	330	10	2	2	223±18
TY 125100	12.5	100	5	330	10	2	2	223±18
TY 15100	15	100	6	330	10	2	2	223±18
TY 20100	20	100	8	330	10	2	2	223±18
TY 23100	23	100	9	330	10	2	2	223±18
TY 25100	25	100	10	330	10	2	2	223±18
TY 30100	30	100	12	330	10	2	2	223±18
TY 35100	35	100	14	330	10	2	2	223±18
TY 38100	38	100	15	330	10	2	2	223±18
TY 40100	40	100	16	330	10	2	2	223±18
TY 45100	45	100	18	330	10	2	2	223±18
TY 50100	50	100	20	330	10	2	2	223±18

5.1. Representative Engineering Drawing of "PMSSteripack Tyvek Sterilization Pouch (TP) with Chemical Indicator"



A: Total width
B: Total height
L: Seal width
V: Single seal width
P: Distance between 2 seals
S: diameter

5.2. Representative Engineering Drawing of "PMSSteripack Tyvek Sterilization Roll (TY) with Chemical Indicator"



A: Total width
B: Total length
L: Seal width
V: Single seal width
P: Distance between 2 seals

6. Description of the Principle of Operation

PMS Steripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator; are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in vaporized hydrogen peroxide (VHP) sterilization method.

Medical device to be sterilized is put into pouch or roll and the open parts of the packages are closed by the end user with heat sealing. Sterilization Pouches then are subjected to sterilization operation in recommended (validated) VHP (Vaporized Hydrogen Peroxide) sterilization devices and cycle as V-PRO 1 PLUS, Lumen Cycle.

Sterilant penetration occurs through the tyvek material into the packages and microorganisms on the surfaces of the enclosed medical devices are destroyed via of the sterilant.

The process indicator on "**PMSSteripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator"** is intended to be used by a health care provider to distinquish between processed and unprocessed units by changing color. Chemical process indicators

on the pouch and/or roll indicate that the pouch or roll has been exposed to sterilization process by changing color.

Chemical process indicators are printed on the pouch and roll **exterior** (printed on tyvek material component) change color when exposed to sterilant vapor during processing. After the sterilization is completed, the sterility of the enclosed medical device is maintained for 30 days. Chemical indicator bars printed on to the medical grade paper component of the pouches are 100 mm^2 size, having dimensions of 5 mmx20 mm.

The indicators used on the pouches are classified as Class 1 type process indicator according to the ISO 11140-1 standard.

7. Comparison of Submission Device and Predicate Device and Substantial Equivalence

Technological characteristics of the submission device and the comparison with predicate device are given in Table 7.1 as a summary. Performance comparison of submission device and predicate device is presented in Table 7.2.

TABLE-7.1: Comparison of Submission Device and Predicate Device (Characteristics)

DEVICE NAME	SUBMISSION DEVICE	PREDICATE DEVICE	SUBSTANTIALLY EQUIVALENCE
CHARACTERISTICS	**PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator**	**STERIS Vis-U-All Low Temperature Sterilization Pouch/Tubing (K140487)**	**YES**
DESIGN AND CONSTRUCTION& MATERIAL COMPOSITION	Tyvek material and heat selaed laminated PET/PE plastic film. Externally printed H2O2 chemical process indicator ink. Pouches are manufactured from tyvek material /plastic film that are heat sealed on 3 sides. The remaining side is left opened and heat sealed by the end user. Rolls are manufactured from tyvek material/plastic film that are heat sealed on opposite two sides. The required size is cut from the roll and the remaining open two sides are heat sealed by the end user.	Pouches are constructed from Tyvek and plastic films, with the Ethylene Oxide Process Chemical Indicator Printed on both sides of Tyvek	**YES**
INDICATIONS FOR USE	PMS Steripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator; are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in vaporized hydrogen peroxide (VHP) sterilization method. PMS Steripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed devices until used.	The Vis-U-All Low Temperature Sterilization Pouches/Tubing is a sterilization containment pouch for use by health care providers to enclose medical devices to be sterilized in Lumen and Non Lumen Cycles in V-PRO 60 Low Temperature Sterilization System. The Pouch maintains the sterility of the enclosed devices until used.	**YES**

The recommended (and validated) sterilization cycle parameters are:

The Steris V-PRO 1 PLUS LUMEN CYCLE is a single preprogramed standard sterilization cycle with NO cycle parameter variables allowed by the end user.

Chemical process indicator on the exterior of the Tyvek pouches and rolls indicates that the pouch has been exposed to V-PRO 1 Plus, Lumen Cycle sterilization process by changing color from red to blue or (lighter).

Devices with stainless steel lumens with the following internal diameter (ID) and maximum length can be processed in V-PRO 1 Plus, Lumen Cycle.

Worst Case Load:

The worst case load for the 50 mm x 200 mm pouch is 0.058 lbs. of instruments.

The worst case load for the 150 mm x 300 mm pouch is 0.630 lbs. of instruments.

The worst case load for the 350 mm x 600 mm pouch is 3.054 lbs. of instruments.

Table 1. Lumen Claims

Pouch Size	Max. lumen length	Min. internal diameter	Max # Lumens
50 x 200 mm	50 mm	1.5 mm	1
150 x 300 mm	3 mm	200 mm	1
350 x 600 mm	3 mm	400 mm	1

Pouches are intended to contain devices in such a manner as to leave a minimum of one inch between the devices and seal on all sides.

Devices with stainless steel lumens and the following minimum internal diameter **(ID)** and maximum length can be processed in Vis-U-All Low Temperature Sterilization Pouch /Tubing using the lumen cycle.

Single or dual lumen devices

- 0.77 mm 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

STERILIZATION PROPERTIES	V-PRO 1 Plus, Lumen Cycle	V-PRO 60 Low Temperature Sterilization System Lumen and Non Lumen Cycles	YES
PRINCIPLE OF OPERATIONS	PMS Steripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator; are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in vaporized hydrogen peroxide (VHP) sterilization method. Medical device to be sterilized is put into pouch or roll and the open parts of the packages are closed by the end user with heat sealing. Sterilization Pouches then are subjected to sterilization operation in recommended (validated) VHP (Vaporized Hydrogen Peroxide) sterilization devices and cycle as V-PRO 1 PLUS, Lumen Cycle. Sterilant penetration occurs through the tyvek material into the packages and microorganisms on the surfaces of the enclosed medical devices are destroyed via of the sterilant. The process indicator on "**PMSSteripack Tyvek Sterilization Pouches (TP) and Rolls (TY) with Chemical Indicator"** is intended to be used by a health care provider to distinquish between processed and unprocessed units by changing color. Chemical process indicators on the pouch and/or roll indicate that the pouch or roll has been exposed to sterilization process by changing color. Chemical process indicators are printed on the pouch and roll **exterior** (printed on tyvek material component) change color when exposed to sterilant vapor during processing. After the sterilization is completed, the sterility of the enclosed medical device is maintained for 30 days. Chemical indicator bars printed on to the medical grade paper component of the pouches are 100 mm^2 size, having dimensions of 5 mmx20 mm. The indicators used on the pouches are classified as Class 1 type process indicator according to the ISO 11140-1 standard.	The Vis-U-All Low Temperature Sterilization Pouches/Tubing is a sterilization containment pouch for use by health care providers to enclose medical devices to be sterilized in Lumen and Non Lumen Cycles in V-PRO 60 Low Temperature Sterilization System. The Pouch maintains the sterility of the enclosed devices until used. Pouches are intended to contain devices in such a manner as to leave a minimum of one inch between the devices and seal on all sides. Devices with stainless steel lumens and the following minimum internal diameter **(ID)** and maximum length can be processed in Vis-U-All Low Temperature Sterilization Pouch /Tubing using the lumen cycle. <u>Single or dual lumen devices</u> • 0.77 mm 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	YES

PRINCIPLES OF OPERATION FOR CHEMICAL INDICATORS	The Process Indicators Ink printed on the tyvek material will exhibit a color change after the pouch is exposed to Hydrogen Peroxide (H2O2) gas. In Hydrogen Peroxide (H2O2) sterilization printed indicator bar changes from **red to blue (or lighter)** when exposed to hydrogen peroxide vapor.	The Process Indicator Ink printed on the tyvek will exhibit a color change after the pouch is exposed to sterilization.	YES
SHELF LIFE (Prior to Sterilizaton)	3 years	2 years	YES
SHELF LIFE (Post Sterilizaton)	30 days	1 year	YES
CONFIGURATIONS& DIMENSIONS	Various sizes (width and height/length)	Various sizes (width and height/length)	YES

TABLE-7.2: Comparison Nonclinical Tests of Submission Device and Predicate Device (Performance)

DEVICE NAME	PROPOSED DEVICE	PREDICATE DEVICE	SUBSTANTIALLY EQUIVALENCE
PERFROMANCE	**"PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator"**	**STERIS Vis-U-All Low Temperature Sterilization Pouch/Tubing (K140487)**	**YES**
Sterilant Penetration	The sterilization (VHP) was validated to a sterility assurance level (SAL) of 10^{-6}	Meets requirements	YES
Microbial Barrier Properties	Sterility was maintained for at least 30 days after processing in V-PRO 1 Plus, Lumen Cycle	Meets requirements	YES
Material Compatibility	Suitability for use in V-PRO 1 Plus, Lumen Cycle sterilization process and cycle parameters.	Meets requirements	YES
Biocompatibility	Not direct patient-contacting devices; Materials are non-toxic and meet ISO 10993-1 requirements.	Meets requirements	YES
Shelf Life (post sterilization)	Sterility was maintained for at least 30 days after processing in V-PRO 1 Plus, Lumen Cycle	Meets requirements	YES
Package Integrity	Porous material providing a microbial barrier.	Meets requirements	YES

8. Conclusion

"PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator" (submission device) and **"Vis-U-All Low Temperature Sterilization Pouch/Tubing" (predicate device)** are both single use devices that are used to enclose another medical device to be sterilized in recommended (validated) sterilization cycles.

PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator and predicate device have many similar technological characteristics. Vis-U-All Low Temperature

Sterilization Pouch/Tubing are made from tyvek material and plastic film by heat sealing. On the other hand**,** PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator and Vis-U-All Low Temperature Sterilization Pouch/Tubing have similar design features and they all have various sizes.

PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator and predicate device have similar sterilization methods (VH2O2). Submission device sterilization system is; VPRO 1 PLUS, Lumen Cycle; Predicate device sterilization system is V-PRO 60 Low Temperature Sterilization System, Lumen and Non Lumen Cycles.

PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator and predicate device have identical performance characteristics considering Sterilant Penetration, Package Integity, Sterility Maintenance, Biocompatibility and Chemical Indicator Efficiacy.

Both the subject device "**PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator"** and the predicate device "**Vis-U-All Low Temperature Sterilization Pouch/Tubing"** meet the requirements of ANSI/ AAMI/ ISO 11140-1:2005 at 50 ^{o}C only and 11607-1:2006/(R)2010.

As indicated in Table 7.2. based on the results of non-clinical performance tests summaries of the subject and predicate device; any differences between subject and predicate device do not impact safety and effectiveness.

In conclusion, the subject device "PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator" is substantially equivalent to predicate device K140487 STERIS Vis-U-All Low Temperature Sterilization Pouch/Tubing. Based on the intended use, technological characteristics, and performance data, the subject PMSSteripack Tyvek Sterilization Pouch (TP) and Roll (TY) with Chemical Indicator, is substantially equivalent and is as safe and as effective as the legally marketed predicate device.