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

October 13, 2017

Pms Tibbi Cihazlar Teknolojisi San Ve Tic As
Derya Dikici
Business Development Manager
Karaduvar Mah.serbest Bolge, 11.cad No.46
Mersin Serbest Bolgesi, Akdeniz
Mersin, 33020 TURKEY

Re: K162362
Trade/Device Name: PMSSteripack Flat Sterilization Pouch (FP) and Roll (FL) with Chemical Indicator
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: FRG, JOJ
Dated: August 24, 2017
Received: September 11, 2017

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); 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), 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,

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)*

K162362

Device Name

PMSSteripack Flat Sterilization Pouch (FP) and Roll(FL) with Chemical Indicator

Indications for Use *(Describe)*

PMSSteripack Flat Sterilization Pouch (FP) and Roll (FL) with Chemical Indicator, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

The recommended (and validated) sterilization cycle parameters for all models (Sterilization Pouches (FP) and Rolls(FL) with Chemical Indicator) are:

- For steam sterilization pre-vacuum cycle at 132 degrees C for 4 minutes. Validated minimum dry time is 20 minutes.
- For EO sterilization; 100%ethylene oxide(EO) with a concentration of 725mg/l at 55 degrees C and 50-80%relative humidity for 60 minutes. Aeration time is 8 hours.

Chemical process indicators on the exterior of the pouch and roll indicate by color change that the pouch has undergone either a steam or ethylene oxide sterilization process.

Type1 steam indicator will change color from **pink to brown** after exposure to pre-vacuum steam sterilization process.

Type 1 ethylene oxide indicator will change from **turquoise to yellow** after exposure to ethylene oxide sterilization process.

As Worst Case Validated Load; general medical devices of stainless steel and devices with stainless steel lumens with the following internal diameter (ID) and Maximum Load weight and Maximum Lumen length can be processed in the validated steam and ETO sterilization cycles as follows;

Table 1.Worst Case Validated Load and Lumen Claims.

Pouch Size	Product Code	Max.Load Weight (lbs.)	Max. lumen length (mm)	Min. internal diameter (mm)	Max # Lumens
50 x 200 mm	FP 0520	0.062	50.8 mm	1.5 mm	1
200 x 300 mm	FP 2030	0.516	200 mm	3.0 mm	1
250 x 300 mm	FP 2530	0.520	200 mm	3.0 mm	1
500 x 600 mm	FP 5060	3.344	400 mm	3.0 mm	1

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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K162362

510 (k) Summary
For
"PMSSteripack Flat Sterilization Pouch (FP) and Roll (FL) with Chemical Indicator"

1.0. Name, address and contact

PMS TIBBI CIHAZLAR TEKNOLOJISI SANAYI VE TICARET ANONIM SIRKETI

Karaduvar Mahallesi, Serbest Bölge 11.cad. No: 46
Mersin Serbest Bölgesi Akdeniz 33020 Mersin –TURKEY

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Prepared by : Taner Ersen
Quality Management Representative

Contact : Derya Dikici
Business Development Manager
Phone : 90 324 2387042- 90 541 648 6312
Fax : 90 324 2386549
E-mail : derya.dikici@pmsmedikal.com

Date Prepared: October 13, 2017

2. Device Name

Trade Name: PMSSteripack Flat Sterilization Pouch (FP) and Roll (FL) with Chemical Indicator

Common/Usual Name: Sterilization Pouch and Roll (Flat)

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

Product Code: FRG – JOJ

Product Classification: Class II

21 CFR 880.6850, General Hospital

3. Predicate Device

K102158, SIGMA Sterilization Pouch and Roll

4. Indications For Use

PMSSteripack Flat Sterilization Pouch (FP) and Roll (FL) with Chemical Indicator, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

The recommended (and validated) sterilization cycle parameters for all models (Sterilization Pouches (FP) and Rolls(FL) with Chemical Indicator) are;

- For steam sterilization pre-vacuum cycle at 132 degrees C for 4 minutes. Validated minimum dry time is 20 minutes.

- For EO sterilization; 100%ethylene oxide(EO) with a concentration of 725mg/l at 55 degrees C and 50-80%relative humidity for 60 minutes. Aeration time is 8 hours.

Chemical process indicators on the exterior of the pouch and roll indicate by color change that the pouch has undergone
either a steam or ethylene oxide sterilization process.

Type 1 steam indicator will change color from **pink to brown** after exposure to pre-vacuum steam sterilization process.

Type 1 ethylene oxide indicator will change from **turquoise to yellow** after exposure to ethylene oxide sterilization process.

As Worst Case Validated Load; general medical devices of stainless steel and devices with stainless steel lumens with the following internal diameter (ID) and Maximum Load weight and Maximum Lumen length can be processed in the validated steam and ETO sterilization cycles as follows;

Table 1.Worst Case Validated Load and Lumen Claims.

Pouch Size	Product Code	Max.Load Weight (lbs.)	Max. lumen length (mm)	Min. internal diameter (mm)	Max # Lumens
50 x 200 mm	FP 0520	0.062	50.8 mm	1.5 mm	1
200 x 300 mm	FP 2030	0.516	200 mm	3.0 mm	1
250 x 300 mm	FP 2530	0.520	200 mm	3.0 mm	1
500 x 600 mm	FP 5060	3.344	400 mm	3.0 mm	1

5. Device Description

PMSSteripack Flat Sterilization pouches (FP) and rolls (FL) with Chemical Indicator; are manufactured from medical grade paper/ laminated PET/PP film, by heat sealing on sides. Triple band seal provides three independent barriers to contamination, while reducing the risk of fiber tear.

PMSSteripack Flat Sterilization Pouches (FP) and Rolls (FL) with Chemical Indicator; are divided into 2 main groups as below;

- Sterilization Pouches, Flat: These pouches are manufactured from medical grade paper/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 medical grade paper/plastic film that is 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.

The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas.

After the sterilization process is completed, the sterility of the enclosed medical device is rnaintained for 30 days.

-List of Model Numbers are given in Table 2 and Table 3.

Table 2. Product List of PMSSteripack Flat Sterilization Pouch (FP) with Chemical Indicator.

PRODUCT LIST (FP)									
Product Name	(A) Total Width (mm) ±2	(B) Total Height (mm) ±5	(A) Total Width (in.) ±0.08	(B) Total Height (in.) ±0.2	(L) Seal Width (mm) ±2	(V) Single Seal Width (mm) min.2	(P) Distance Between 2 Seals (mm) ±0.1	(S) Diameter (mm) min.	(T) Thickness (µm)
FP0520	50	200	2	8	10	2	2	10	153±18
FP0525	50	250	2	10	10	2	2	10	153±18
FP0530	50	300	2	12	10	2	2	10	153±18
FP0532	50	320	2	12¾	10	2	2	10	153±18
FP0535	50	350	2	14	10	2	2	10	153±18
FP7515	75	150	3	6	10	2	2	10	153±18
FP7518	75	180	3	7	10	2	2	10	153±18

FP7520	75	200	3	8	10	2	2	10	153±18
FP7523	75	230	3	9	10	2	2	10	153±18
FP7525	75	250	3	10	10	2	2	10	153±18
FP7528	75	280	3	11	10	2	2	10	153±18
FP7530	75	300	3	12	10	2	2	10	153±18
FP7535	75	350	3	14	10	2	2	10	153±18
FP7540	75	400	3	16	10	2	2	10	153±18
FP7545	75	450	3	18	10	2	2	10	153±18
FP0815	80	150	3¼	6	10	2	2	10	153±18
FP0817	80	170	3¼	6¾	10	2	2	10	153±18
FP0818	80	180	3¼	7	10	2	2	10	153±18
FP0820	80	200	3¼	8	10	2	2	10	153±18
FP0827	80	270	3¼	10¾	10	2	2	10	153±18
FP0860	80	600	3¼	24	10	2	2	10	153±18
FP0956	90	560	3½	22	10	2	2	10	153±18
FP0960	90	600	3½	24	10	2	2	10	153±18
FP0961	90	610	3½	24	10	2	2	10	153±18
FP1015	100	150	4	6	10	2	2	10	153±18
FP1018	100	180	4	7	10	2	2	10	153±18
FP1019	100	190	4	7½	10	2	2	10	153±18
FP1020	100	200	4	8	10	2	2	10	153±18
FP1023	100	230	4	9	10	2	2	10	153±18
FP1025	100	250	4	10	10	2	2	10	153±18
FP1026	100	260	4	10¼	10	2	2	10	153±18
FP1027	100	270	4	10¾	10	2	2	10	153±18
FP1028	100	280	4	11	10	2	2	10	153±18
FP1030	100	300	4	12	10	2	2	10	153±18
FP1033	100	330	4	13	10	2	2	10	153±18
FP1035	100	350	4	14	10	2	2	10	153±18
FP1036	100	360	4	14	10	2	2	10	153±18
FP1040	100	400	4	16	10	2	2	10	153±18
FP1045	100	450	4	18	10	2	2	10	153±18
FP1050	100	500	4	20	10	2	2	10	153±18
FP1056	100	560	4	22	10	2	2	10	153±18
FP1057	100	570	4	22	10	2	2	10	153±18
FP1060	100	600	4	24	10	2	2	10	153±18
FP1061	100	610	4	24	10	2	2	10	153±18
FP1128	110	280	4¼	11	10	2	2	10	153±18
FP1225	120	250	4¾	10	10	2	2	10	153±18
FP1230	120	300	4¾	12	10	2	2	10	153±18

FP1240	120	400	4¾	16	10	2	2	10	153±18
FP1250	120	500	4¾	20	10	2	2	10	153±18
FP1325	130	250	5	10	10	2	2	10	153±18
FP1338	130	380	5	15	10	2	2	10	153±18
FP1520	150	200	6	8	10	2	2	10	153±18
FP1525	150	250	6	10	10	2	2	10	153±18
FP1527	150	270	6	10¾	10	2	2	10	153±18
FP1528	150	280	6	11	10	2	2	10	153±18
FP1530	150	300	6	12	10	2	2	10	153±18
FP1532	150	320	6	12¾	10	2	2	10	153±18
FP1535	150	350	6	14	10	2	2	10	153±18
FP1538	150	380	6	15	10	2	2	10	153±18
FP1540	150	400	6	16	10	2	2	10	153±18
FP1543	150	430	6	17	10	2	2	10	153±18
FP1545	150	450	6	18	10	2	2	10	153±18
FP1550	150	500	6	20	10	2	2	10	153±18
FP1552	150	520	6	20¼	10	2	2	10	153±18
FP1555	150	550	6	22	10	2	2	10	153±18
FP1556	150	560	6	22	10	2	2	10	153±18
FP1640	160	400	6¼	16	10	2	2	10	153±18
FP1658	160	580	6¼	23	10	2	2	10	153±18
FP1722	170	220	6¾	8¾	10	2	2	10	153±18
FP1735	170	350	6¾	14	10	2	2	10	153±18
FP1830	180	300	7	12	10	2	2	10	153±18
FP1832	180	320	7	12¾	10	2	2	10	153±18
FP1846	180	460	7	18	10	2	2	10	153±18
FP1933	190	330	7½	13	10	2	2	10	153±18
FP2020	200	200	8	8	10	2	2	10	153±18
FP2025	200	250	8	10	10	2	2	10	153±18
FP2027	200	270	8	10¾	10	2	2	10	153±18
FP2030	200	300	8	12	10	2	2	10	153±18
FP2033	200	330	8	13	10	2	2	10	153±18
FP2035	200	350	8	14	10	2	2	10	153±18
FP2040	200	400	8	16	10	2	2	10	153±18
FP2041	200	410	8	16	10	2	2	10	153±18
FP2045	200	450	8	18	10	2	2	10	153±18
FP2050	200	500	8	20	10	2	2	10	153±18
FP2060	200	600	8	24	10	2	2	10	153±18
FP2128	210	280	8¼	11	10	2	2	10	153±18
FP2135	210	350	8¼	14	10	2	2	10	153±18

FP2140	210	400	8¼	16	10	2	2	10	153±18
FP2142	210	420	8¼	16¾	10	2	2	10	153±18
FP2228	220	280	8¾	11	10	2	2	10	153±18
FP2235	220	350	8¾	14	10	2	2	10	153±18
FP2242	220	420	8¾	16¾	10	2	2	10	153±18
FP2525	250	250	10	10	10	2	2	10	153±18
FP2530	250	300	10	12	10	2	2	10	153±18
FP2535	250	350	10	14	10	2	2	10	153±18
FP2538	250	380	10	15	10	2	2	10	153±18
FP2540	250	400	10	16	10	2	2	10	153±18
FP2545	250	450	10	18	10	2	2	10	153±18
FP2550	250	500	10	20	10	2	2	10	153±18
FP2735	270	350	10¾	14	10	2	2	10	153±18
FP2745	270	450	10¾	18	10	2	2	10	153±18
FP2835	280	350	11	14	10	2	2	10	153±18
FP2840	280	400	11	16	10	2	2	10	153±18
FP2845	280	450	11	18	10	2	2	10	153±18
FP2850	280	500	11	20	10	2	2	10	153±18
FP2857	280	570	11	22	10	2	2	10	153±18
FP3038	300	380	12	15	10	2	2	10	153±18
FP3040	300	400	12	16	10	2	2	10	153±18
FP3042	300	420	12	16¾	10	2	2	10	153±18
FP3045	300	450	12	18	10	2	2	10	153±18
FP3046	300	460	12	18	10	2	2	10	153±18
FP3050	300	500	12	20	10	2	2	10	153±18
FP3055	300	550	12	22	10	2	2	10	153±18
FP3060	300	600	12	24	10	2	2	10	153±18
FP3245	320	450	12¾	18	10	2	2	10	153±18
FP3250	320	500	12¾	20	10	2	2	10	153±18
FP3255	320	550	12¾	22	10	2	2	10	153±18
FP3346	330	460	13	18	10	2	2	10	153±18
FP3540	350	400	14	16	10	2	2	10	153±18
FP3545	350	450	14	18	10	2	2	10	153±18
FP3550	350	500	14	20	10	2	2	10	153±18
FP3552	350	520	14	20¼	10	2	2	10	153±18
FP3555	350	550	14	22	10	2	2	10	153±18
FP3660	360	600	14	24	10	2	2	10	153±18
FP4040	400	400	16	16	10	2	2	10	153±18
FP4045	400	450	16	18	10	2	2	10	153±18
FP4055	400	550	16	22	10	2	2	10	153±18

FP4060	400	600	16	24	10	2	2	10	153±18
FP4141	410	410	16	16	10	2	2	10	153±18
FP4150	410	500	16	20	10	2	2	10	153±18
FP4241	420	410	16¾	16	10	2	2	10	153±18
FP4250	420	500	16¾	20	10	2	2	10	153±18
FP4255	420	550	16¾	22	10	2	2	10	153±18
FP4260	420	600	16¾	24	10	2	2	10	153±18
FP4656	460	560	18	22	10	2	2	10	153±18
FP4661	460	610	18	24	10	2	2	10	153±18
FP4858	480	580	19	23	10	2	2	10	153±18
FP5060	500	600	20	24	10	2	2	10	153±18

Table 3. Product List of PMSSteripack Flat Sterilization Roll (FL) with Chemical Indicator.

PRODUCT LIST (FL)								
Product Name	**(A) Total Width (cm) ±0.2**	**(B) Total Length (m) ±%1**	**(A) Total Width (in) ±0.008**	**(B) Total Length (ft) ±%1**	**(L) Seal Width (mm) ±2**	**(V) Single Seal Width (mm) min.2**	**(P) Distance Between 2 Seals (mm) ±0.1**	**(T) Thickness (µm)**
FL 0530	5	30	2	100	10	2	2	153±18
FL 7530	7.5	30	3	100	10	2	2	153±18
FL 1030	10	30	4	100	10	2	2	153±18
FL 12530	12.5	30	5	100	10	2	2	153±18
FL 1530	15	30	6	100	10	2	2	153±18
FL 2030	20	30	8	100	10	2	2	153±18
FL 2330	23	30	9	100	10	2	2	153±18
FL 2530	25	30	10	100	10	2	2	153±18
FL 3030	30	30	12	100	10	2	2	153±18
FL 3530	35	30	14	100	10	2	2	153±18
FL 3830	38	30	15	100	10	2	2	153±18
FL 4030	40	30	16	100	10	2	2	153±18
FL 4530	45	30	18	100	10	2	2	153±18
FL 5030	50	30	20	100	10	2	2	153±18
FL 0560	5	60	2	200	10	2	2	153±18
FL 7560	7.5	60	3	200	10	2	2	153±18
FL 1060	10	60	4	200	10	2	2	153±18
FL 12560	12.5	60	5	200	10	2	2	153±18
FL 1560	15	60	6	200	10	2	2	153±18

FL 2060	20	60	8	200	10	2	2	153±18
FL 2360	23	60	9	200	10	2	2	153±18
FL 2560	25	60	10	200	10	2	2	153±18
FL 3060	30	60	12	200	10	2	2	153±18
FL 3560	35	60	14	200	10	2	2	153±18
FL 3860	38	60	15	200	10	2	2	153±18
FL 4060	40	60	16	200	10	2	2	153±18
FL 4560	45	60	18	200	10	2	2	153±18
FL 5060	50	60	20	200	10	2	2	153±18
FL 05100	5	100	2	330	10	2	2	153±18
FL 75100	7.5	100	3	330	10	2	2	153±18
FL 10100	10	100	4	330	10	2	2	153±18
FL 125100	12.5	100	5	330	10	2	2	153±18
FL 15100	15	100	6	330	10	2	2	153±18
FL 20100	20	100	8	330	10	2	2	153±18
FL 23100	23	100	9	330	10	2	2	153±18
FL 25100	25	100	10	330	10	2	2	153±18
FL 30100	30	100	12	330	10	2	2	153±18
FL 35100	35	100	14	330	10	2	2	153±18
FL 38100	38	100	15	330	10	2	2	153±18
FL 40100	40	100	16	330	10	2	2	153±18
FL 45100	45	100	18	330	10	2	2	153±18
FL 50100	50	100	20	330	10	2	2	153±18
FL 05200	5	200	2	656	10	2	2	153±18
FL 75200	7.5	200	3	656	10	2	2	153±18
FL 10200	10	200	4	656	10	2	2	153±18
FL 125200	12.5	200	5	656	10	2	2	153±18
FL 15200	15	200	6	656	10	2	2	153±18
FL 20200	20	200	8	656	10	2	2	153±18
FL 23200	23	200	9	656	10	2	2	153±18
FL 25200	25	200	10	656	10	2	2	153±18
FL 30200	30	200	12	656	10	2	2	153±18
FL 35200	35	200	14	656	10	2	2	153±18
FL 38200	38	200	15	656	10	2	2	153±18
FL 40200	40	200	16	656	10	2	2	153±18
FL 45200	45	200	18	656	10	2	2	153±18
FL 50200	50	200	20	656	10	2	2	153±18

6. Description of the Principle of Operation

PMSSteripack Sterilization Pouches (FP) and Rolls (FL) with Chemical Indicator, are used to enclose medical devices that are to be sterilized by health care provider via sterilization methods. Medical device to be sterilized is put into roll or pouch and the open parts of the packages are closed by heat sealing. Sterilization packages then are subjected to sterilization operation in related sterilization devices (steam sterilizers, EO sterilization devices). Sterilant penetration is carried out through the medical grade paper into the packages and microorganisms on the surface of the medical devices are destroyed with the effect of the sterilant vapors. Other parameters of the sterilization process are temperature, pressure; humidity and time are deteminded according to the sterilization type.

The process indicator on the pouches and rolls are intended to be used by a health care provider with sterilization pouches to distinguish between processed and unprocessed units by changing color. Chemical process indicators on the pouch and roll indicate that the pouch has been exposed to sterilization process by changing color.

Chemical process indicators are printed on the pouch or roll (printed on medical grade paper) changes 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 pouch and roll are classified as Class 1 type Indicator according to the ISO 11140-1 standard. The steam and ETO chemical indicator inks used in the PMS FL and FP sterilization pouches have been commercially available for many years and both indicator inks were cleared by the FDA in a prior PMS 510k pouch submission under No. K152669.

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

Technological characteristics of the submission device and the comparison with predicate devices are given in table 7.1 as a summary.

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

<table>
<tr><th>DEVICE NAME</th><th>SUBMISSION DEVICE</th><th>PREDICATE DEVICE</th><th>COMPARISON</th></tr>
<tr><td>CHARACTERISTICS</td><td>PMSSteripack Flat Sterilization Pouch(FP) and Roll (FL) with Chemical Indicator</td><td>SIGMA Sterilization Pouch and Roll (K102158)</td><td></td></tr>
<tr><td>DESIGN AND CONSTRUCTION& MATERIAL COMPOSITION</td><td>Medical grade paper and heat selaed laminated PET/PP plastic film. Externally printed Steam and EO process indicator ink.

The pouches are manufactured from medical grade paper and heat sealed laminated PET/PP plastic film that is heat sealed on 3 sides. The remaining open side is heat sealed by the end user.

Rolls are manufactured from medical grade paper and heat sealed laminated PET/PP plastic film that is 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.</td><td>Medical Grade Paper and heat sealed plastic film. EO and Steam Process Indicator Print ink. Pouches are made from a medical grade plastic film that is heat sealed on three sides. The forth side is left opened and is heat-sealed when using. In gusseted pouches, plastic film is folded on both longest sides. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas.</td><td>Similar</td></tr>
<tr><td>INTENDED USE</td><td>PMSSteripack Flat Sterilization Pouch (FP) and Roll (FL) with Chemical Indicator, is a device intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.

The indicated sterilization parameters for either steam or EO are the only validated sterilization parameters to be used/applied.

<u>The recommended (and validated) sterilization cycle parameters for all models (Sterilization Pouches (FP) and Rolls(FL) with Chemical Indicator) are;</u>

• For steam sterilization pre-vacuum cycle at 132 degrees C for 4 minutes. Validated minimum dry time is 20 minutes.
• For EO sterilization; 100%ethylene oxide(EO) with a concentration of 725mg/l at 55 degrees C and 50-80%relative humidity for 60 minutes. Aeration time is 8 hours.

Chemical process indicators on the exterior of the pouch and roll indicate by color change that the pouch has undergone either a steam or ethylene oxide sterilization process.

Class 1 steam indicator will change color from pink to brown after exposure to pre-vacuum steam sterilization process.

Class 1 ethylene oxide indicator will change from turquoise to yellow after exposure to ethylene oxide sterilization process.

As Worst Case Validated Load; general medical devices of stainless steel and devices with stainless steel lumens with the following internal diameter (ID) and Maximum Load weight and Maximum Lumen length can be processed in the validated steam and ETO sterilization cycles as follows;

<table>
<tr><th>Pouch Size</th><th>Product Code</th><th>Max. Load Weight (lbs.)</th><th>Max. lumen length (mm)</th><th>Min. internal diameter (mm)</th><th>Max # Lumens</th></tr>
<tr><td>50 x 200 mm</td><td>FP 0520</td><td>0.062</td><td>50.8 mm</td><td>1.5 mm</td><td>1</td></tr>
<tr><td>200 x 300 mm</td><td>FP 2030</td><td>0.516</td><td>200 mm</td><td>3.0 mm</td><td>1</td></tr>
<tr><td>250 x 300 mm</td><td>FP 2530</td><td>0.520</td><td>200 mm</td><td>3.0 mm</td><td>1</td></tr>
<tr><td>500 x 600 mm</td><td>FP 5060</td><td>3.344</td><td>400 mm</td><td>3.0 mm</td><td>1</td></tr>
</table>
Table 1.Worst Case Validated Load and Lumen Claims.</td><td>Single use devices, to enclose other medical devices that are to be sterilized by a health provider. Sterilization pouch and roll are intended to provide health care workers with an effective method to enclose devices intended for sterilization in steam auto claves and via Ethylene Oxide (EO).

The recommended steam sterilization cycle parameters are 30 minutes at 121 ^{o}C.

The recommended EO sterilization cycle is 4 hours at 55 ^{o}C with a relative humidity between 50%-85% and a sterilant concentration of 600 mg/L.

Furthermore, the sterilization pouch and roll maintains the enclosed devices up until 3 years post sterilization.

Lastly, the pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.</td><td>The intended use differences are minor and does not impact substantial equivalence</td></tr>
</table>

STERILIZATION PROPERTIES	The recommended(validated) sterilization cycle parameters are; For Steam sterilization; pre-vacuum cycle at 132 ^{o}C for 4 minutes. For EO Sterilization; 100% ethylene oxide (EO) with a concentration of 725 mg/L at 55 ^{o}C and 50-80% relative humidity for 60 minutes. Aeration time is 8 hours.	The recommended steam sterilization cycle parameters are 30 minutes at 121 ^{o}C. The recommended EO sterilization cycle is 4 hours at 55 ^{o}C with a relative humidity between 50%/85% and a sterilant concentration of 600 mg/L.	Similar
PRINCIPLE OF OPERATION	Medical device to be sterilized is put into pouch or roll and the open parts of the packages are closed by heat sealing. Sterilization packages then are subjected to validated sterilization operation of steam or EO. Sterilant penetration is carried out through the medical grade paper into the package and microorganisms on the surface of the medical device are destroyed with the effect of the sterilant vapors. Other parameters of the sterilization process are temperature, pressure, humidity, time and are determined according to the sterilization type. Chemical process indicator is printed **exterior** on the pouch/roll (printed on medical grade paper) changes 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	Medical device to be sterilized is put into roll or pouch and the open parts of the packages are closed by heat sealing. Sterilization packages then are subjected to sterilization operation in related sterilization devices (steam autoclaves, EO sterilization). The process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas. The SIGMA sterilization pouch and roll is offered in the **following 5 types:** * Self-sealing sterilization pouches * Sterilization pouches, Flat * Sterilization pouches, Gusseted * Sterilization rolls, Flat * Sterilization rolls, Gusseted	Similar
PRINCIPLES OF OPERATION FOR CHEMICAL INDICATORS	The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas. In steam sterilization, printed indicator bar changes from **pink to brown** when exposed to steam. In EO sterilization, printed indicator bar changes from **tuquoise to yellow** when expoed to EO gas.	The Process Indicators Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam or ethylene oxide gas.	Similar
SHELF LIFE (**pre-sterilization use**)	5 years	3 years	The testing supports substantial equivalence.
SHELF LIFE (post sterilization)	30 days	3 years	The testing supports substantial equivalence.
CONFIGURATIONS& DIMENSIONS	Various sizes (width and height/length)	Various sizes (width, height/length and gusset)	Similar

TABLE-7.2: Comparison of Submission Device and Predicate Device (Non-Clinical Performance Testing)

DEVICE NAME	PROPOSED DEVICE	PREDICATE DEVICE	COMPARISON
PERFROMANCE (Test Standard)	**PMSSteripack Flat Sterilization Pouch (FP) and Roll (FL) with Chemical Indicator**	**SIGMA Sterilization Pouch and Roll (K102158)**	Similar
Sterilant Penetration (AAMI TIR 12)	passed	passed	Similar
Microbial Barrier Properties (ANSI/AAMI/ISO 14937)	passed	passed	Similar
Material Compatibility (ISO 10993-5)	passed	passed	Similar
Biocompatibility (ISO 10993-5)	passed	passed	Similar
Shelf Life (post sterilization) (ANSI/AAMI/ISO 11607-1)	passed	passed	Similar
Drying Time (AAMI TIR 12)	passed	passed	Similar
Aeration Time (ISO 10993-7)	passed	passed	Similar
Package Integrity (ANSI/AAMI/ISO 11607-1)	passed	passed	Similar

8. Discussion - Safety and Effectiveness

The PMSSteripack Flat Sterilization pouch (FP) and roll (FL) has the same intended use and substantially equivalent indication for use as the predicate devices. Substantial equivalence was established by testing sterilant penetration, drying time, aeration, biocompatibility, package integrity, materials compatibility, sterility maintenance and chemical indicator efficacy.

The PMSSteripack Flat Sterilization pouch (FP) and roll (FL) validates its effectiveness and safety using recommended practice, standards and guidelines developed by independent organizations, such as the Association for the advancement of Medical Instrumentation (AAMI), International Organization for Standardization (ISO), and American Society for Testing and Materials (ASTM). The PMSSteripack Flat Sterilization pouch (FP) and roll (FL) was validated to meet the requirements of ANSI/AAMIISO 11607-1:2006/A1 2014.

The results of the PMSSteripack Flat Sterilization pouch (FP) and roll (FL) validation studies demonstrate that the sterilization pouches perform as intended. The results are summarized as follows:

- The Sterilant Penetration, Drying Time, Aeration, testing performed as described in ANSI/AAMI/ISO 17665-1:2006/R2013, ISO 17665-2:2009, ANSI/AAMI/ISO 11135-2014, AAMI TIR 12 2010, ANSI/AAMI/ISO 10993-7:2008/R 2012 and ISO 17025:2005. The testing results demonstrate the ability of the PMSSteripack Flat Sterilization pouch (FP) and roll (FL) to effectively allow adequate sterilant penetration to the most difficult areas to reach inside the packaging. The results confirm that the sterilant is able to penetrate the PMSSteripack Flat Sterilization pouch (FP) and roll (FL) and sustain direct contact with the medical instrument inside the package. And the result of aeration time validation test meets the

requirements ANSI/AAMI/ISO I0993-7:2008/R 2012.

- The Biocompatibility testing performed as described in ANSI/AAMI/ISO 10993-5:2009 and ISO 17025:2005. The testing results demonstrate the PMSSteripack Flat Sterilization pouch (FP) and roll (FL) did not elicit any cytotoxic effect.

- The Package Integrity, Material Compatibility, Sterility Maintenance testing performed as described in ANSI/AAMI/ISO 11607-1:2006/A1 2014, ASTM F1140/F1140M - 13, ASTM F88-09, ASTM D882-12, ISO 1924-2 , ASTM F1929-12, ASTM D645-97, ASTM F2251-13, ISO 1974-12, ASTM D1922-09, ASTM F1886-09, ASTM F2096-11, ANSI/AAMI/ISO 14937:2009/R2013 and ISO 17025:2005. The testing results demonstrate the ability of the PMSSteripack Flat Sterilization pouch (FP) and roll (FL) to effectively withstand the sterilization process, while allowing sterilization to occur and to retain sterility (Package Integrity) of the sterilized contents till point of use.

- The Chemical Indicator Efficacy testing was performed as described in ANSI/AAMI/ISO 11140-1:2014 for a class 1 process indicator. The testing demonstrates the ability of the steam and EtO process indicators on the PMSSteripack Flat Sterilization pouch (FP) and roll (FL) to reproducibly meet their performance specifications throughout the shelf life of the pouch and roll. The PMSSteripack Flat Sterilization pouch (FP) and roll (FL) meets the requirements ISO 11140-1:2014.

Any differences between the predicate and proposed device concerning materials, manufacturing or intended use are insignificant and they do not impact the safety or effectiveness of the subject device.

Any differences between the predicate and proposed device performance testing are insignificant and they do not impact the safety or effectiveness of the subject device. The main difference noted is that the PMSSteripack Flat Sterilization pouch (FP) and roll (FL) were tested with the latest versions of the same standards.

PMSSteripack Flat Sterilization pouch (FP) and roll (FL) with Chemical Indicator **(subject device)** and SIGMA Sterilization pouch and roll **(predicate device)** are both single use devices that are used to enclose another medical device to be sterilized in required sterilization methods by the end user.

PMSSteripack Flat Sterilization pouch (FP) and roll (FL) with Chemical Indicator and predicate device apply substantially equivalent technological characteristics. SIGMA Sterilization pouch and rolls are made from medical grade paper and laminated plastic film by heat sealing. PMSSteripack Sterilization pouch and roll and SIGMA Sterilization pouch and roll have the equivalent material and design features and they all have various size.

PMSSteripack Flat Sterilization pouch (FP) and roll (FL) with Chemical Indicator and predicate device have equivalent sterilization methods (Steam and ETO).

9. 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 the legally marketed predicate device (K102158), Class II 21 CFR 880.6850 (FRG-JOJ).