



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 15, 2016

PMS Tip Teknolojileri Sanayi Ve Ticaret Limited, STI
Ms. Derya Dikici
Business Development Manager
Mersin Tarsus Organize Sanayi Bolgesi, 12 CAD, No. 2
Huzurkent, Mersin, TR 33020

Re: K152669
Trade/Device Name: PMSSteripack Self Seal Sterilization Pouch with Chemical
Indicator (KP)
Regulation Number: 21 CFR 880.6850
Regulation Name: Wrap, Sterilization
Regulatory Class: II
Product Code: FRG; JOJ
Dated: December 10, 2015
Received: December 16, 2015

Dear Ms. 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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
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Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K152669

Device Name
PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP)

Indications for Use (Describe)

PMSSteripack Self Seal Sterilization Pouches with Chemical Indicator (KP); are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization with steam or ethylene oxide (EO) applying the below validated sterilization cycle parameters. The indicated sterilization parameters for either steam or EO are the only validated sterilization parameters to be used/applied.

The recommended (and validated) sterilization cycle parameters are;

- For steam sterilization pre-vacuum cycle at 132 degrees C for 4 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 indicator on the exterior of the pouch indicates by color change that the pouch has undergone either a steam or ethylene oxide sterilization process.

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

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**510 (k) Summary for
PMSSteripack Self Seal Sterilization Pouch with
Chemical Indicator (KP)**

1. Name, address and contact

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Business Development Manager

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Date Prepared: December 07, 2015

2. Device Name

Trade Name: PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator

Common/Usual Name: Sterilization Pouch (Self Seal)

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

Product Code: 1) FRG 2) JOJ

Product Classification: Class II

21 CFR 880.6850, General Hospital (FRG)

21 CFR 880.2800(b), General Hospital (JOJ)

3. Predicate Device

K102158, SIGMA Sterilization Pouch and Roll

4. Indications for Use/Intended Use

PMSSteripack Self Seal Sterilization Pouches with Chemical Indicator (KP) are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization with steam or ethylene oxide (EO) applying the below validated sterilization cycle parameters. The indicated sterilization parameters for either steam or EO are the only validated sterilization parameters to be used/applied.

The recommended (and validated) sterilization cycle parameters are:

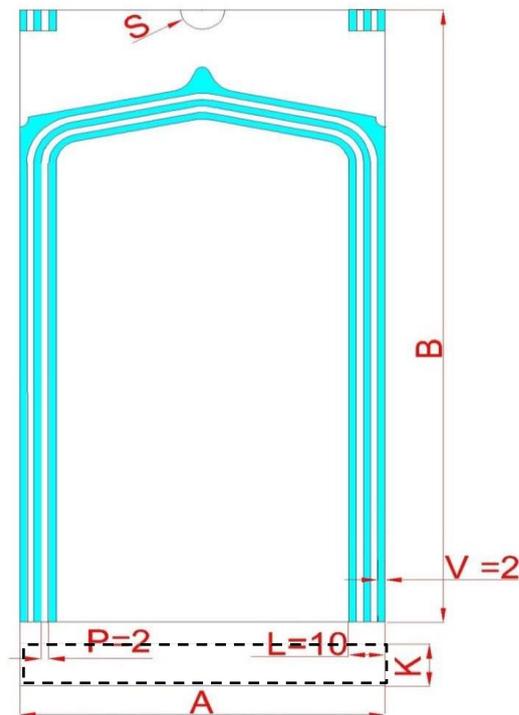
- For steam sterilization pre-vacuum cycle at 132 degrees °C for 4 minutes.
- For EO sterilization; 100% ethylene oxide (EO) with a concentration of 725mg/l 55 degrees C and 50-80% relative humidity for 60 minutes. Aeration time is 8hrs.

Chemical process indicator on the exterior of the pouch indicates by color change that the pouch has undergone either a steam or ethylene oxide sterilization process. After the sterilization process is completed the sterility of the enclosed medical device is maintained for 30 days.

5. Device Description

PMSSteripack Self Seal Sterilization Pouches with Chemical Indicator (KP); are manufactured from medical grade paper/plastic film that are heat sealed on 3 sides, the fourth side has a self-seal adhesive strip and left opened. This side is manually sealed by the user with the self-seal adhesive strip. Triple band seal provides three independent barriers to contamination, while reducing the risk of fibre tear. PMSSteripack Self Seal Sterilization Pouches with Chemical Indicator (KP); are presented as 60 gsm model.

Representative Engineering Drawing: “PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP)”



- A: Total width
- B: Total height
- L: Seal width (mm)
- V: Single seal width (mm)
- P: Distance between 2 seals (mm)
- S: Diameter
- K: Strip width

6. Description of the Principle of Operation

PMSSteripack Self Seal Sterilization Pouches with Chemical Indicator (KP) 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 pouch and the open parts of the packages are manually closed with the self-seal adhesive strip. 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 determined according to the sterilization type.

The process indicator on the pouches 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 indicate that the pouch has been exposed to sterilization process by changing color.

Chemical process indicators are printed on the pouch exterior (printed on medical grade paper component) 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 mm² 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 devices are given in Table 7.1. as a summary.

TABLE 7.1. Comparison of Submission Device and Predicate Device (Characteristics)

DEVICE NAME	SUBMISSION DEVICE	PREDICATE DEVICE	SE
CHARACTERISTICS	PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP)	SIGMA Sterilization Pouch and Roll (K102158)	YES
DESIGN AND CONSTRUCTION & MATERIAL COMPOSITION	Medical grade paper and heat sealed laminated PET/PP plastic film. Externally printed Steam and EO process indicator ink. Pouches are manufactured from medical grade paper/plastic film that are heat sealed on 3 sides, the fourth side is left opened and has an adhesive strip which is used to seal the pouch.	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. Self seal pouche has an adhesive strip that is used to seal the pouch. Release paper used in the pouch is a laminated sheet with composing structure of FE/paper/PE. It is a strip to cover the adhesive area and is released before seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas.	YES

<p>INTENDED USE</p>	<p>Single use devices to enclose other medical devices that are to be sterilized by health care provider via Steam and Ethylene Oxide (EO) sterilization methods. The recommended (and validated) sterilization cycle parameters are; For Steam sterilization pre-vacuum cycle at 132 °C for 4 minutes. For EO sterilization; 100% ethylene oxide with a concentration of 725 mg/L, at 55 °C and 50-80% relative humidity for 60 minutes. Aeration time is 8 hours. Chemical process indicators on the pouch indicate that the pouch has been exposed to sterilization process by changing color. After the sterilization is completed, the sterility of the enclosed medical device is maintained for 30 days.</p>	<p>Single use devices, to enclose another medical devices that is 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).</p> <p>The recommended steam sterilization cycle parameters are 30 minutes at 121 °C.</p> <p>The recommended EO sterilization cycle is 4 hours at 55 °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.</p>	<p>YES</p>
<p>STERILIZATION PROPERTIES</p>	<p>The recommended (and validated) sterilization cycle parameters are; For Steam sterilization pre-vacuum cycle at 132 °C for 4 minutes. For EO Sterilization; 100% ethylene oxide (EO) with a concentration of 725 mg/L at 55 °C and 50-80% relative humidity for 60 minutes. Aeration time is 8 hours.</p>	<p>The recommended steam sterilization cycle parameters are 30 minutes at 121 °C.</p> <p>The recommended EO sterilization cycle is 4 hours at 55 °C with a relative humidity between 50%/85% and a sterilant concentration of 600 mg/L.</p>	<p>YES</p>
<p>PRINCIPLE OF OPERATION</p>	<p>Medical device to be sterilized is put into pouch and the open part of the package is closed manually with an adhesive strip. Sterilization packages then are subjected to validated sterilization operation of steam & 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 (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.</p>	<p>Medical device to be sterilized is put into roll or pouch and the open parts of the packages are closed by self sealing. Sterilization packages then are subjected to sterilization operation in related sterilization devices (steam autoclaves, EO sterilization).</p> <p>The process Indicators Ink printed on the medical grade paper will pouch is exposed to steam or ethylene oxide gas. The SIGMA sterilization pouch and roll is offered in the following 5 types:</p> <ul style="list-style-type: none"> * Self-sealing sterilization pouches * Sterilization pouches, Flat * Sterilization pouches, Gusseted * Sterilization rolls, Flat * Sterilization rolls, Gusseted 	<p>YES</p>
<p>PRINCIPLES OF OPERATION FOR CHEMICAL INDICATORS</p>	<p>The Process Indicator Ink printed on the medical grade paper will exhibit a color change after the pouch is exposed to steam and 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 turquoise to yellow when exposed to EO gas.</p>	<p>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.</p>	<p>YES</p>

SHELF LIFE	5 years	3 years	YES
CONFIGURATIONS& DIMENSIONS	Various sizes (width and height)	Various sizes (width, height and gusset)	YES

TABLE 7.2. Comparison of Submission Device and Predicate Device (Performance)

DEVICE NAME	PROPOSED DEVICE	PREDICATE DEVICE	SUBSTANTIALLY EQUIVALENCE
PERFROMANCE	PMS Steripack Self Seal Sterilization pouch with Chemical Indicator	SIGMA sterilization Pouch and Roll (K102158)	YES
Sterilant Penetration	The sterilization (steam and EO) was validated to a sterility assurance level (SAL) of 10^{-6}	Sterility assurance level of 10^{-6} achieved.	YES
Microbial Barrier Properties	Sterility was maintained for at least 30 days after processing in Steam and EO sterilizer.	Meets requirements	YES
Material Compatibility	Suitability for use in Steam and EO sterilization processes 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
Package Integrity	Porous material providing a microbial barrier.	Meets requirements	YES

8. Conclusion

PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP) (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.

PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP) and predicate device have many similar technological characteristics. SIGMA Sterilization pouch and rolls are made from medical grade paper and laminated plastic film by heat sealing. On the other hand, PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP) and SIGMA Sterilization pouch and roll have the same design features and they all have various size.

PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP) and predicate device have similar sterilization methods (Steam and EO).

PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP) and predicate device have similar performance characteristics considering Sterilant Penetration, Drying Time, Aeration time, Package Integrity, Sterility Maintenance, Biocompatibility and Chemical Indicator Efficiency.

Both the subject device PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP) and the predicate devices SIGMA Sterilization pouch and roll meet the requirements of ANSI/ AAMI/ ISO 11140-1:2005 and ANSI/ AAMI/ ISO 11607-1:2006.

In conclusion, the subject device PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP) is substantially equivalent to predicate device K102158 SIGMA Sterilization Pouches and Rolls. Based on the intended use, technological characteristics, and performance data, the subject PMSSteripack Self Seal Sterilization Pouch with Chemical Indicator (KP) is substantially equivalent and is as safe and as effective as the legally marketed predicate device.