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

August 4, 2016

Safe Secure Packaging Co., Ltd
% Mr. Brian Edwards
Senior Medical Research Manager, Regulatory
NAMSA
4050 Olson Memorial Highway
Golden Valley, MN 55422

Re: K153540
Trade/Device Name: Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: FRG
Dated: July 11, 2016
Received: July 12, 2016

Dear Mr. Edwards:

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 yours,

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)*
K153540

Device Name
Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators

Indications for Use *(Describe)*

Safe Secure Paper Sterilization Pouches and Rolls are intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider using:

- Gravity steam at 121°C (250°F) for 30 minutes; 25 minutes dry time
- Pre-vacuum steam at 132°C (270°F) for 4 minutes; 20 minutes dry time
- Pre-vacuum steam at 134°C (273°F) for 3 minutes; 20 minutes dry time
- Pre-vacuum steam at 135°C (275°F) for 3 minutes; 16 minutes dry time
- Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60ºC (140ºF).

The device is not intended and has not been validated for sterilization of devices that contain lumens.

The external chemical indicators on the pouches/rolls are intended to demonstrate that the device has been exposed to the steam or EO sterilization process and to distinguish between processed and unprocessed devices. The chemical indicators change from green to purple after exposure to steam and from yellow to brown after exposure to ethylene oxide.

The Tyvek version of the pouch is for EO sterilization only.

If stored according to the recommended conditions, the products before sterilization have a maximum shelf life of 5 years from the date of manufacture. The pouches are intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility (SAL=10^{-6}). The subject device is intended and has been validated to maintain sterility of the enclosed devices for 6 months after steam sterilization and 24 months after EO sterilization.

The maximum validated pouch load is 2.64 pounds (1.2kg).

The following tables list the available model numbers of the Safe Secure Sterilization Pouches and Rolls.

Table 1: Safe Secure Medical Grade Paper Sterilization Pouch/Roll Products

Model	Type	Sterilization Cycle(s)	Dimensions(mm)	
			Width (mm)	Length (mm)
ABHSP100001	POUCH PAPER HEAT SEAL 3.5X10	Steam or Ethylene Oxide	89	254
ABHSP100002	POUCH PAPER HEAT SEAL 7.5X13	Steam or Ethylene Oxide	191	330
ABHSP100003	POUCH PAPER HEAT SEAL 6X10	Steam or Ethylene Oxide	152	254
ABHSP100004	POUCH PAPER HEAT SEAL 4.5X11	Steam or Ethylene Oxide	114	279
ABHSP100005	POUCH PAPER HEAT SEAL 5X15	Steam or Ethylene Oxide	127	381
ABHSP100006	POUCH PAPER HEAT SEAL 10X15	Steam or Ethylene Oxide	254	381
ABHSP100007	POUCH PAPER HEAT SEAL 18X22	Steam or Ethylene Oxide	457	559
ABHSP100008	POUCH PAPER HEAT SEAL 12X18	Steam or Ethylene Oxide	305	457
ABHSP100009	POUCH PAPER HEAT SEAL 4X8	Steam or Ethylene Oxide	102	203
ABHSP100010	POUCH PAPER HEAT SEAL 3X8	Steam or Ethylene Oxide	76	203
ABHSP100011	POUCH PAPER HEAT SEAL 16X16	Steam or Ethylene Oxide	406	406
ABHSP100012	POUCH PAPER HEAT SEAL 4X22	Steam or Ethylene Oxide	102	559
ABHSP100013	POUCH PAPER HEAT SEAL 13X15	Steam or Ethylene Oxide	330	381
ABHSP100014	POUCH PAPER HEAT SEAL 8X10	Steam or Ethylene Oxide	203	254
ABHSP100015	POUCH PAPER HEAT SEAL 8X16	Steam or Ethylene Oxide	203	406
ABHSP110001	TUBING PAPER 6IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	151	30500

Model	Type	Sterilization Cycle(s)	Dimensions(mm)	
			Width (mm)	Length (mm)
ABHSP110002	TUBING PAPER 9IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	228	30500
ABHSP110003	TUBING PAPER 4IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	101	30500
ABHSP110004	TUBING PAPER 3IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	75	30500
ABHSP110005	TUBING PAPER 12IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	305	30500
ABHSP110006	TUBING PAPER 2IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	51	30500
ABHSP120001	POUCH MULTIPLE INNER 8 POUCHES SHEET	Steam or Ethylene Oxide	230	415
ABHSP120002	POUCH MULTIPLE INNER 4 POUCHES SHEET	Steam or Ethylene Oxide	230	415
ABSSP100001	POUCH PAPER SELF SEAL 7.5X13	Steam or Ethylene Oxide	191	353
ABSSP100002	POUCH PAPER SELF SEAL 5.25X10	Steam or Ethylene Oxide	140	277
ABSSP100003	POUCH PAPER SELF SEAL 13X18	Steam or Ethylene Oxide	330	480
ABSSP100004	POUCH PAPER SELFSEAL 12X15	Steam or Ethylene Oxide	305	404
ABSSP100005	POUCH PAPER SELF SEAL 3.5X8.75	Steam or Ethylene Oxide	89	245
ABSSP100006	POUCH PAPER SELF SEAL 5X15	Steam or Ethylene Oxide	127	404
ABSSP100007	POUCH PAPER SELF SEAL 3.5X9.875	Steam or Ethylene Oxide	89	274
ABSSP100008	POUCH PAPER SELF SEAL 8X16	Steam or Ethylene Oxide	203	429
ABSSP100009	POUCH PAPER SELF SEAL 3.5X22	Steam or Ethylene Oxide	89	582
ABSSP100010	POUCH PAPER SELF SEAL 9.125X25.5	Steam or Ethylene Oxide	232	671
ABSSP100011	POUCH PAPER SELF SEAL 4X11	Steam or Ethylene Oxide	102	302

Table 2: Safe Secure Tyvek Sterilization Pouch/Roll Products

Model	Type	Sterilization Cycle(s)	Dimensions(mm)	
			Width (mm)	Length (mm)
ABSST100001	POUCH TYVEK SELF SEAL 8X12	Ethylene Oxide Only	203	345
ABSST100002	POUCH TYVEK SELF SEAL 6X10	Ethylene Oxide Only	152	294
ABSST100003	POUCH TYVEK SELF SEAL 12X18	Ethylene Oxide Only	305	497
ABSST100004	POUCH TYVEK SELF SEAL 10X15	Ethylene Oxide Only	254	421
ABSST100005	POUCH TYVEK SELF SEAL 4X9	Ethylene Oxide Only	102	269
ABSST100006	POUCH TYVEK SELF SEAL 3X7	Ethylene Oxide Only	76	218
ABSST100007	POUCH TYVEK SELF SEAL 4X12	Ethylene Oxide Only	102	345
ABSST100008	POUCH TYVEK SELF SEAL 4X22	Ethylene Oxide Only	102	599
ABHST100001	POUCH TYVEK HEAT SEAL 8X12	Ethylene Oxide Only	203	305
ABHST100002	POUCH TYVEK HEAT SEAL 6X10	Ethylene Oxide Only	152	254
ABHST100003	POUCH TYVEK HEAT SEAL 10X15	Ethylene Oxide Only	254	381
ABHST100004	POUCH TYVEK HEAT SEAL 12X18	Ethylene Oxide Only	305	457
ABHST100005	POUCH TYVEK HEAT SEAL 4X12	Ethylene Oxide Only	102	305
ABHST100006	POUCH TYVEK HEAT SEAL 4X9	Ethylene Oxide Only	102	229
ABHST100007	POUCH TYVEK HEAT SEAL 4X22	Ethylene Oxide Only	102	559
ABHST100008	POUCH TYVEK HEAT SEAL 3X7	Ethylene Oxide Only	76	178
ABHST110001	TUBING TYVEK 9IN WIDTH 75FT ROLL	Ethylene Oxide Only	228	22900
ABHST110002	TUBING TYVEK 6IN WIDTH 75FT ROLL	Ethylene Oxide Only	151	22900
ABHST110003	TUBING TYVEK 4IN WIDTH 75FT ROLL	Ethylene Oxide Only	101	22900
ABHST110004	TUBING TYVEK 3IN WIDTH 75FT ROLL	Ethylene Oxide Only	75	22900

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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5.0 510(k) Summary

5.1 Submission Sponsor

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5.2 Submission Correspondent

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5.3 Date Prepared

August 1, 2016

5.4 Device Identification

Trade/Proprietary Name:	Safe Secure Sterilization Pouches with Steam and Ethylene Oxide Process Indicators
Common/Usual Name:	Sterilization Pouch
Classification Name:	Sterilization Wrap
Classification Regulation:	21 CFR Part 880.6850
Product Code:	FRG
Device Class:	II
Classification Panel:	General Hospital
Model Numbers:	ABHSP, ABSSP, ABHST, ABSST

5.5 Predicate Devices

K112591 - Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators

5.6 Device Description

The Safe Secure Sterilization Pouches are made from either a medical grade porous paper or Tyvek thermally sealed to a plastic film on the left, right, and bottom of the pouch. The top side is open in order to receive the medical device to be sterilized and to seal the pouch. They are available either pre-manufactured self-seal or heat-seal sizes or in a roll of heat-seal tubing for the customer to cut the pouches to their required size.

The base model numbers for the subject device are described as follows, where the last three letters corresponds to the type of material:

- ABSST – Self seal Tyvek
- ABHST – Heat seal Tyvek
- ABHSP – Heat seal paper
- ABSSP – Self seal paper

The pouches also contain external chemical indicators used to indicate that the pouches have been processed by either a steam or ethylene oxide sterilization process.

The medical grade paper versions can be used in either gravity steam, pre-vacuum steam, or ethylene oxide (EO) sterilization cycles. The Tyvek version is only for EO sterilization.

5.7 Indication for Use

Safe Secure Paper Sterilization Pouches and Rolls are intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider using:

- Gravity Steam at 121°C (250°F) for 30 minutes; 25 minutes dry time
- Pre-vacuum Steam at 132°C (270°F) for 4 minutes; 20 minutes dry time
- Pre-vacuum Steam at 134°C (273°F) for 3 minutes; 20 minutes dry time
- Pre-vacuum steam at 135°C (275°F) for 3 minutes; 16 minutes dry time
- Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60°C (140°F).

The device is not intended and has not been validated for sterilization of devices that contain lumens.

The external chemical indicators on the pouches/rolls are intended to demonstrate that the device has been exposed to the Steam or EO sterilization process and to distinguish between processed and unprocessed devices. The chemical indicators change from green to purple after exposure to steam and from yellow to brown after exposure to ethylene oxide.

The Tyvek version of the pouch is for EO sterilization only.

If stored according to the recommended conditions, the products before sterilization have a maximum shelf life of 5 years from the date of manufacture. The pouches are intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility (SAL=10^{-6}). The subject device is intended and has been validated to maintain sterility of the enclosed devices for 6 months after steam sterilization and 24 months after EO sterilization.

The maximum validated pouch load is 2.64 pounds (1.2kg).

These products are to be used for medical products without lumens.

The follow table list the available model numbers of the Safe Secure Sterilization Pouches and Rolls.

Table 1: Safe Secure Medical Grade Paper Sterilization Pouch/Roll Products

Model	Type	Sterilization Cycle(s)	Dimensions (mm)	
			Width (mm)	Length (mm)
ABHSP100001	POUCH PAPER HEAT SEAL 3.5X10	Steam or Ethylene Oxide	89	254
ABHSP100002	POUCH PAPER HEAT SEAL 7.5X13	Steam or Ethylene Oxide	191	330
ABHSP100003	POUCH PAPER HEAT SEAL 6X10	Steam or Ethylene Oxide	152	254
ABHSP100004	POUCH PAPER HEAT SEAL 4.5X11	Steam or Ethylene Oxide	114	279
ABHSP100005	POUCH PAPER HEAT SEAL 5X15	Steam or Ethylene Oxide	127	381
ABHSP100006	POUCH PAPER HEAT SEAL 10X15	Steam or Ethylene Oxide	254	381
ABHSP100007	POUCH PAPER HEAT SEAL 18X22	Steam or Ethylene Oxide	457	559
ABHSP100008	POUCH PAPER HEAT SEAL 12X18	Steam or Ethylene Oxide	305	457
ABHSP100009	POUCH PAPER HEAT SEAL 4X8	Steam or Ethylene Oxide	102	203
ABHSP100010	POUCH PAPER HEAT SEAL 3X8	Steam or Ethylene Oxide	76	203
ABHSP100011	POUCH PAPER HEAT SEAL 16X16	Steam or Ethylene Oxide	406	406
ABHSP100012	POUCH PAPER HEAT SEAL 4X22	Steam or Ethylene Oxide	102	559
ABHSP100013	POUCH PAPER HEAT SEAL 13X15	Steam or Ethylene Oxide	330	381
ABHSP100014	POUCH PAPER HEAT SEAL 8X10	Steam or Ethylene Oxide	203	254
ABHSP100015	POUCH PAPER HEAT SEAL 8X16	Steam or Ethylene Oxide	203	406
ABHSP110001	TUBING PAPER 6IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	151	30500
ABHSP110002	TUBING PAPER 9IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	228	30500
ABHSP110003	TUBING PAPER 4IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	101	30500
ABHSP110004	TUBING PAPER 3IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	75	30500
ABHSP110005	TUBING PAPER 12IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	305	30500

Model	Type	Sterilization Cycle(s)	Dimensions (mm)	
			Width (mm)	Length (mm)
ABHSP110006	TUBING PAPER 2IN WIDTH 100FT ROLL	Steam or Ethylene Oxide	51	30500
ABHSP120001	POUCH MULTIPLE INNER 8 POUCHES SHEET	Steam or Ethylene Oxide	230	415
ABHSP120001	POUCH MULTIPLE INNER 4 POUCHES SHEET	Steam or Ethylene Oxide	230	415
ABSSP100001	POUCH PAPER SELF SEAL 7.5X13	Steam or Ethylene Oxide	191	353
ABSSP100002	POUCH PAPER SELF SEAL 5.25X10	Steam or Ethylene Oxide	140	277
ABSSP100003	POUCH PAPER SELF SEAL 13X18	Steam or Ethylene Oxide	330	480
ABSSP100004	POUCH PAPER SELFSEAL 12X15	Steam or Ethylene Oxide	305	404
ABSSP100005	POUCH PAPER SELF SEAL 3.5X8.75	Steam or Ethylene Oxide	89	245
ABSSP100006	POUCH PAPER SELF SEAL 5X15	Steam or Ethylene Oxide	127	404
ABSSP100007	POUCH PAPER SELF SEAL 3.5X9.875	Steam or Ethylene Oxide	89	274
ABSSP100008	POUCH PAPER SELF SEAL 8X16	Steam or Ethylene Oxide	203	429
ABSSP100009	POUCH PAPER SELF SEAL 3.5X22	Steam or Ethylene Oxide	89	582
ABSSP100010	POUCH PAPER SELF SEAL 9.125X25.5	Steam or Ethylene Oxide	232	671
ABSSP100011	POUCH PAPER SELF SEAL 4X11	Steam or Ethylene Oxide	102	302

Table 2: Safe Secure Tyvek Sterilization Pouch/Roll Products

Model	Type	Sterilization Cycle(s)	Dimensions (mm)	
			Width (mm)	Length (mm)
ABSST100001	POUCH TYVEK SELF SEAL 8X12	Ethylene Oxide Only	203	345
ABSST100002	POUCH TYVEK SELF SEAL 6X10	Ethylene Oxide Only	152	294
ABSST100003	POUCH TYVEK SELF SEAL 12X18	Ethylene Oxide Only	305	497
ABSST100004	POUCH TYVEK SELF SEAL 10X15	Ethylene Oxide Only	254	421
ABSST100005	POUCH TYVEK SELF SEAL 4X9	Ethylene Oxide Only	102	269
ABSST100006	POUCH TYVEK SELF SEAL 3X7	Ethylene Oxide Only	76	218
ABSST100007	POUCH TYVEK SELF SEAL 4X12	Ethylene Oxide Only	102	345
ABSST100008	POUCH TYVEK SELF SEAL 4X22	Ethylene Oxide Only	102	599
ABHST100001	POUCH TYVEK HEAT SEAL 8X12	Ethylene Oxide Only	203	305
ABHST100002	POUCH TYVEK HEAT SEAL 6X10	Ethylene Oxide Only	152	254
ABHST100003	POUCH TYVEK HEAT SEAL 10X15	Ethylene Oxide Only	254	381
ABHST100004	POUCH TYVEK HEAT SEAL 12X18	Ethylene Oxide Only	305	457
ABHST100005	POUCH TYVEK HEAT SEAL 4X12	Ethylene Oxide Only	102	305
ABHST100006	POUCH TYVEK HEAT SEAL 4X9	Ethylene Oxide Only	102	229
ABHST100007	POUCH TYVEK HEAT SEAL 4X22	Ethylene Oxide Only	102	559
ABHST100008	POUCH TYVEK HEAT SEAL 3X7	Ethylene Oxide Only	76	178
ABHST110001	TUBING TYVEK 9IN WIDTH 75FT ROLL	Ethylene Oxide Only	228	22900

Model	Type	Sterilization Cycle(s)	Dimensions (mm)	
			Width (mm)	Length (mm)
ABHST110002	TUBING TYVEK 6IN WIDTH 75FT ROLL	Ethylene Oxide Only	151	22900
ABHST110003	TUBING TYVEK 4IN WIDTH 75FT ROLL	Ethylene Oxide Only	101	22900
ABHST110004	TUBING TYVEK 3IN WIDTH 75FT ROLL	Ethylene Oxide Only	75	22900

5.8 Comparison to Predicates

The Safe Secure Sterilization Pouches are substantially equivalent to the previous pouch version cleared under K112591 – Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators.

Safe Secure Sterilization Pouch Substantial Equivalence Table

Item #		**Safe Secure Sterilization Pouch (Predicate Device)**	**Safe Secure Sterilization Pouch (Subject Device)**	
1	**510(k) Number**	K112591	TBD	
2	**Manufacturer**	Safe Secure Packaging (Shenzhen) Co., Ltd No.4 Chengguang Industrial Park,Guanlan Street, Baoan District,Shenzhen,518110 China	Safe Secure Packaging (Shenzhen) Co., Ltd No.4 Chengguang Industrial Park, Guanlan Street, Baoan District,Shenzhen,518110 China	Same
3	**Model Numbers**	ABHSP, ABSSP	ABHSP, ABSSP, ABHST, ABSST	Substantial Equivalent
4	**Classification**	II	II	Same
5	**Product Code**	FRG	FRG	Same
6	**Regulation**	21 CFR 880.6850	21 CFR 880.6850	Same

Item #		Safe Secure Sterilization Pouch (Predicate Device)	Safe Secure Sterilization Pouch (Subject Device)	
7	**Indications for Use**	Safe Secure Sterilization Pouch with Steam and Ethylene Oxide Process Indicators (Heat-seal and Self-seal) is intended to be used to enclose another medical device that is to be sterilized by a health provider by gravity steam and ethylene oxide (EO). The recommended steam sterilization cycle parameters is 30 minutes at 121°C (250°F). The recommended EO gas sterilization cycle is greater than or equal to 735mg/L of ethylene oxide (EO) for 1 hour at 55℃ (130 °F)) and 50% to 80%RH. The pouch's external chemical ink indicators on the pouches are intended to demonstrate that the device has been expose to the steam or EO sterilization process and to distinguish between processed and unprocessed devices. The pouch is intended to allow sterilization of the enclosed medical device and also to maintain sterility (SAL= 10^{-6}) of the enclosed device until used.	Safe Secure Paper Sterilization Pouches and Rolls are intended to be used to enclose another medical device, in a single or double pouch configuration, that is to be sterilized by a health care provider using: •Gravity Steam at 121℃ (250°F) for 30 minutes •Pre-vacuum Steam at 132℃ (270°F) for 4 minutes •Pre-vacuum Steam at 134℃ (273°F) for 3 minutes •Pre-vacuum steam at 135℃ (275°F) for 3 minutes •Ethylene Oxide (EO) with a concentration of 735 mg/L at 55°C (131°F) and 50% to 80% relative humidity for 60 minutes. Aeration time of 8 hours at 60°C (140°F). The external chemical indicators on the pouches/rolls are intended to demonstrate that the device has been exposed to the Steam or EO sterilization process and to distinguish between processed and unprocessed devices. The Tyvek version of the pouch is for EO sterilization only. If stored according to the recommended conditions, the products before sterilization have a maximum shelf life of 5 years from the date of manufacture. The pouches are intended to allow sterilization of the enclosed medical device(s) and also to maintain sterility (SAL=10^{-6}). The maximum validated pouch load is 2.64 pounds (1.2kg). These products are to be used for	Substantially Equivalent
8	**Material Composition**	Porous paper or Tyvek, PET/CPP high-temperature blue compound film, High temperature adhesive paper, Medical Double Side Tape, EO gas indicator ink, Steam indicator ink.	Porous paper or Tyvek, PET/CPP high-temperature blue compound film, High temperature adhesive paper, Medical Double Side Tape, EO gas indicator ink, Steam indicator ink.	Same

Item #		Safe Secure Sterilization Pouch (Predicate Device)	Safe Secure Sterilization Pouch (Subject Device)	
9	**Pouch Dimensions***	Length: 2 to 20 inches Width: 8 to 30 inches	Length: 2 to 20 inches Width: 8 to 30 inches	Same
10	**Roll Dimensions**	Width: 8 to 30 inches	Width: 8 to 30 inches	Same
11	**Air Permeance**	The maximum equivalent pore size diameter shall not exceed 50um.	The maximum equivalent pore size diameter shall not exceed 50um.	Same
12	**Shelf Life**	5 years before sterilization; 6 months after gravity steam sterilization or 24 months after EOsterilization	5 years before sterilization; 6 months after steam sterilization (gravity or pre-vacuum) or 24 months after EOsterilization	Same
13	**Paper and Film Thickness & Density**	Paper: ±2 gm/m^2 Film: + 0.002 mm Tyvek: ±2 gm/m^2	Paper: ±2 gm/m^2 Film: + 0.002 mm Tyvek: ±2 gm/m^2	Same
14	**Seal Strength before sterilization**	2.5 to 5.5 N/15mm	2.5 to 5.5 N/15mm	Same
15	**Seal strength after steam sterilization**	2.5 to 5.5 N/15mm	> 1.5 N / 15mm	Substantially Equivalent
16	**Seal strength after EO sterilization**	2.5 to 5.5 N/15mm	> 1.5 N / 15mm	Substantially Equivalent
17	**Burst Strength**	2.5 to 5.5 N/15mm	2.5 to 5.5 N/15mm	Same
18	**Peel-Open**	No splitting of paper more than 10mm from heat seal lines	No splitting of paper more than 10mm from heat seal lines	Same
19	**Tensile Strength**	Paper: > 220 N/50mm Film: > 550 N/50mm Tyvek: > 250 N/50mm	Paper: > 220 N/50mm Film: > 550 N/50mm Tyvek: > 250 N/50mm	Same
20	**Seal Integrity**	Visual examination of the seal area through the transparent side of the package shows no channels present.	Visual examination of the seal area through the transparent side of the package shows no channels present.	Same
21	**Seal Width**	More than 8mm	More than 8mm	Same
22	**Limits for acidity or alkalinity**	The PH value of an extract prepared shall be within one PH unit of that of the control fluid	The PH value of an extract prepared shall be within one PH unit of that of the control fluid	Same
23	**Limits for extractable metals**	Shall not contain greater than a combined total of 5 mg/ml of lead, zinc, or iron	Shall not contain greater than a combined total of 5 mg/ml of lead, zinc, or iron	Same
24	**EO Residual Limits**	Less than 1 mg/pouch/day	Less than 1 mg/pouch/day	Same
25	**Chemical Process Indicators**	For Steam Sterilization: Green to Purple For EO Sterilization: Yellow to Brown	For Steam Sterilization: Green to Purple For EO Sterilization: Yellow to Brown	Same

*Nominal Length and Width is determined by Product Code ordered.

5.9 Functional Testing

To verify that the Safe Secure Sterilization Pouches meet the design requirements after exposure to the three new pre-vacuum steam sterilization cycles, and continue to meet the requirements after being exposed to the already cleared gravity steam and ethylene oxide cycles, testing was conducted in accordance with ASTM and ISO standards relating to sterile packaging of medical devices. In addition, biocompatibility and shelf-life stability testing was performed.

The following bench performance tests were performed to support substantial equivalence.

- Visual Appearance
- Seal Integrity
- Dimensional Size
- Seal Width
- Seal Leak
- Seal Strength
- Sterilization Indicator Test
- Biological Indicator Test
- Accelerated Aging and Shelf-Life Tests
- Half and full cycle sterilization validation using worst case load configurations
- Dry time validation using worst case load configurations

The following biocompatibility tests were performed to support substantial equivalence.

- Cytotoxicity
- Maximization Sensitization
- Irritation

In all instances, the addition of the Pre-Vacuum Sterilization Cycles did not affect the pouch performance.

5.10 Conclusion

Based on the intended use, indications for use, technological characteristics, performance data and nonclinical tests performed, the subject device, the Safe Secure Sterilization Pouch with added pre-vacuum sterilization cycles is substantially equivalent and as safe and as effective as the legally marketed predicate devices, K112591, Safe Secure Sterilization pouch.