February 7, 2018

SteriZign Precision Technologies, LLC
% Robert Dean
President
Compliance Systems International, LLC
1083 Delaware Ave.
Buffalo, New York 14209

Re: K171520
Trade/Device Name: SteriZign Signatur Device Protection System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: January 8, 2018
Received: January 12, 2018

Dear Robert Dean:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: 0MB No. 0910-0120
Expiration Date: January 31, 2017

510(k) Number *(if known) K171520*

Device Name
SteriZign Signatur Device Protection System

Indications for Use *(Describe)*

Identification: A sterilization wrap (pack, sterilization wrapper, bag, or accessories, 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.

SteriZign Signatur Device Cassette and Trays are used to organize, transport, store and protect between uses of surgical and other medical devices that are sterilized by a healthcare provider. SteriZign Signatur Device Cassette and Trays are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycles. The SteriZign Signatur Device Cassette and Trays are not intended on their own to maintain sterility. SteriZign Signatur Device Cassette and Trays have perforations and intended to be used in conjunction with legally marketed, validated FDA cleared sterilization wrap.

Autoclave Sterilization Parameter Cycle:
Pre-vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Dry Time: 30 minutes

The total weight of a tray (e.g. tray, insert and instruments) should never exceed 25 lbs.

Validated sizes of stainless steel instrument lumens include:

1 each 1mm x 76 mm
1 each 1mm x 400 mm
1 each 2mm x 400 mm
1 each 3mm x 400 mm
1 each 5mm x 400 mm

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW. –**

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, inciuding suggestions for reducing this burden, to:

Department of Health and Human Services Food
and Drug Administration
Office of Chief Information Officer Paperwork
Reduction Act (PRA) Staff *PRAStaff@fda.hhs.gov*

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid 0MB number."

510(k) Summary
K171520
SteriZign Precision Technologies, LLC

I. Company: SteriZign Precision Technologies, LLC
74 Orion Street
Brunswick, ME 04011
888-234-3074

II. Contact: Sonia Lutarewych
President
(206) 510-3650

Date : January 31, 2018

Device Name: SteriZign Signatur Device Protection System
Common Name: Sterilization cassette/trays
Classification: Sterilization Wrap Containers, Cassettes/trays , Cassettes & Accessories.
(21 CFR 880.6850)

Class: II

Product Code: KCT

III. Predicate Devices: Cassettes/trays - K133015 Summit Medical, Instrusafe Instrument Protection System.

IV. Description:
SteriZign Signatur Device Protection System are cassettes/trays used to enclose and hold surgical instruments and accessories in an organized manner during the sterilization process and subsequent storage and transportation. The cassettes/trays by themselves do not maintain sterility. The cassettes/trays are different sizes of the same basic configuration: a rectangular base with a cover. The cassettes/trays have perforations to allow sterilant penetration. The cassettes/trays contain silicone inserts in the base and/or cover to hold, organize and protect the surgical instruments within the cassettes/trays .

V. Indications for Use:
Identification: A sterilization wrap (pack, sterilization wrapper, bag, or accessories, 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.

SteriZign Signatur Device Protection System are used to organize, transport, store and protect between uses of surgical and other medical devices that are sterilized by a healthcare provider. SteriZign Signatur Device Protection System are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycles. The SteriZign Signatur Device Protection System are not intended on their own to maintain sterility. The SteriZign Signatur Device Protection System have perforations and intended to be used in conjunction with legally marketed, validated FDA cleared sterilization wrap.

Autoclave Sterilization Parameter Cycle:
Pre-vacuum
Temperature: 270°F (132°C)
Exposure Time: 4 minutes
Dry Time: 30 minutes

The total weight of a tray (e.g. tray, insert and instruments) should never exceed 25 lbs.

Validated sizes of stainless steel instrument lumens include:

1 each 1mm x 76 mm
1 each 1mm x 400 mm
1 each 2mm x 400 mm
1 each 3mm x 400 mm
1 each 5mm x 400 mm

VI. Device List

CATALOG PART NUMBER	Cassette - Tray Size	Vent to Volume Ratio
102010-3	**9.86"X20.46"X3.58"**	0.075
122010-3	10"X20"X3"	0.231
121610-3	10"X16"X3"	0.225
121410-3	10"X14"X3"	0.232
120910-3	10"X9.3"X3"	0.228
122010-4	10"X20"X4"	0.197
121610-4	10"X16"X4"	0.195
121410-4	10"X14"X4"	0.203
120910-4	10"X9.3"X4"	0.184
122010-5	10"X20"X5"	0.173
121610-5	10"X16"X5"	0.172
121410-5	10"X14"X5"	0.172
120910-5	10"X9.3"X5"	0.165
112410-3	10"X24"X3"	0.158
112010-3	10"X20"X3"	0.152
111610-3	10"X16"X3"	0.152
111410-3	10"X14"X3"	0.146
110910-3	10"X9.3"X3"	0.139
112410-4	10"X24"X4"	0.128
112010-4	10"X20"X4"	0.123
111610-4	10"X16"X4"	0.124
111410-4	10"X14"X4"	0.121
110910-4	10"X9.3"X4"	0.117
112410-5	10"X24"X5"	0.11
112010-5	10"X20"X5"	0.107
111610-5	10"X16"X5"	0.105
111410-5	10"X14"X5"	0.105
110910-5	10"X9.3"X5"	0.103
202557-190	25"X5.75"X1.9"	0.522
202535-190	25"X3.5"X1.9"	0.561
202057-190	20"X5.75"X1.9"	0.514
202035-190	20"X3.5"X1.9"	0.563
201757-190	17.6"X5.75"X1.9"	0.508
201757-190	17.6"X3.5"X1.9"	0.543
201457-190	14"X5.75"X1.9"	0.504
201435-190	14"X3.5""X1.9"	0.548
201157-190	11"X5.75""X1.9"	491
201135-190	11"X3.5""X1.9"	0.543
301610-630	16"X10"X6.3"	0.156

302210-630	22.6"X10"X6.3"	0.131
302610-630	26"X10"X6.3"	0.132
401510-166	15.61"X10.44"X1.66"	0.428
401006-166	10.61"X6.44"X1.66"	0.413
400606-166	6.61"X6.44"X1.66"	0.423
400603-166	6.61"X3.44"X1.66"	0.345
ACCESSORIES	**Inner Trays**	
902309-250	23.24"X9.4"2.5"	NA
902309-200	23.24"X9.4"2.0"	NA
902309-125	23.24"X9.4"1.25"	NA
901909-250	19.24"X9.4"2.5"	NA
901909-200	19.24"X9.4"2.0"	NA
901909-125	19.24"X9.4"1.25"	NA
901509-250	15.24"X9.4"2.5"	NA
901509-200	15.24"X9.4"2.0"	NA
901509-125	15.24"X9.4"1.25"	NA
901309-250	13.24"X9.4"2.5"	NA
901309-200	13.24"X9.4"2.0"	NA
901309-125	13.24"X9.4"1.25"	NA
900809-250	8.54"X9.4"2.5"	NA
900909-200	8.54"X9.4"2.0"	NA
900909-125	8.54"X9.4"1.25"	NA
912309-250	23.24"X9.4"2.5"	NA
912309-200	23.24"X9.4"2.0"	NA
912309-125	23.24"X9.4"1.25"	NA
911909-250	19.24"X9.4"2.5"	NA
911909-200	19.24"X9.4"2.0"	NA
911909-125	19.24"X9.4"1.25"	NA
911509-250	15.24"X9.4"2.5"	NA
911509-200	15.24"X9.4"2.0"	NA
911509-125	15.24"X9.4"1.25"	NA
911309-250	13.24"X9.4"2.5"	NA
911309-200	13.24"X9.4"2.0"	NA
911309-125	13.24"X9.4"1.25"	NA
910909-250	8.54"X9.4"2.5"	NA
910909-200	8.54"X9.4"2.0"	NA
910909-125	8.54"X9.4"1.25"	NA

510(k) Summary
K171520
SteriZign Precision Technologies, LLC

VII Comparative Chart

Company	SteriZign	Substantially Equivalent (Y/N)	Summit Medical Instru-Safe
Trade Name	**SteriZign Signatur Device Protection System**	**Y**	**Instru-Safe® Instrument Protection System**
FDA 510K #	**K171520**	**-**	**K133015**
Intended Use	Identification: A sterilization wrap (pack, sterilization wrapper, bag, or accessories, 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. SteriZign Signatur Device Protection System are used to organize, transport, store and protect between uses of surgical and other medical devices that are sterilized by a healthcare provider. SteriZign Signatur Device Protection System are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycles. The SteriZign Signatur Device Protection System are not intended on their own to maintain sterility. The SteriZign Signatur Device Protection System have perforations and intended to be used in conjunction with legally marketed, validated FDA cleared sterilization wrap. Autoclave Sterilization Parameter Cycle: Pre-vacuum Temperature: 270°F (132°C) Exposure Time: 4 minutes Dry Time: 30 minutes The total weight of a tray (e.g. tray, insert and instruments) should never exceed 25 lbs. Validated sizes of stainless steel instrument lumens include: 1 each 1mm x 76 mm 1 each 1mm x 400 mm 1 each 2mm x 400 mm 1 each 3mm x 400 mm 1 each 5mm x 400 mm	**Y**	Instru -Safe Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru -Safe Instrument Protection System cassettes are intend to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycles. Instru -Safe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. Instru -Safe Instrument Protection System cassettes are not intended on their own to maintain sterility. Autoclave Sterilization Parameter Cycle: Pre-Vacuum Temperature: 270 degrees F (132 degrees C) Exposure Time: 4 minutes Minimum Dry Time: 30 minutes
Lumen Claims	**Lumen Inner Diameter (ID) x Length** 1 mm 76 mm 1 mm 400 mm 2 mm 300 mm 3 mm 400 mm 5 mm 400 mm	**Y**	**Lumen Inner Diameter (ID) x Length** 1 mm x 76 mm 1mm x 65mm 1 mm x 400 mm 2 mm x 300 mm 3 mm x 177 mm 3 mm x 200mm 3 mm x 400 mm 5 mm x 241 mm
Max Weight	The total weight of the container system (e.g. container, tray and instrument load) must not exceed 25 lbs.	**Y**	17 lbs.
Classification Monograph	880.6850	**Y**	880.6850

510(k) Summary
K171520
SteriZign Precision Technologies, LLC

Regulation Name	Sterilization Wrap	**Y**	Sterilization Wrap
Class	2	**Y**	2
Class Code	KCT	**Y**	KCT
Predicate 510K	Summit K133015	**N/A**	Not Indicated in 510k Statement
Description	SteriZign Signatur Device Protection System are cassettes/ trays used to enclose and hold surgical instruments and accessories in an organized manner during the sterilization process and subsequent storage and transportation. The cassettes / trays by themselves do not maintain sterility	**Y**	Instru-Safe Instrument Protection System cassettes include - perforated base - perforated cover - silicone inserts (hold-it / hold down) - handles -latches - feet - posts (optional) - divider (optional) - Shelf (optional)
Material Composition	Base: Aluminum Anodized Insert: Aluminum Anodized Lid: Aluminum Anodized Latch: 300 Series SS Passivated Handle: 300 Series SS Passivated Shelf Bracket: 300 Series SS Passivated Mat(s): Silicone Brackets: Polypropylene	**Y**	Anodized Aluminum lid and base silicone brackets Stainless Steel latch Stainless Steel handles Anodized aluminum bar holders Polypropylene feet Silicone dividers Silicone mats Stainless steel brackets Locating post - High performance plastic (Radel or Delrin) Accessory box- High performance plastic Delrin or Radel
Sterilization parameters	Sterilant (steam) penetration through perforations in tray PreVacuum, 132 degrees C/270 Degrees F, 4 minute cycle with 30 dry time	**Y**	From Summit Medical 510K 133015 "*Validated by Summit Medical for use in steam prevacuum sterilizers ONLY operating at 270oF (132oC) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization containers load claims."
Microbial Barrier Properties	SteriZign Signatur Device Protection System is intended to be used in conjunction with a legally marketed wrap. The SteriZign Signatur Device Protection System are not intended on their own to maintain sterility	**Y**	The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility.
Air Permeance	Yes	**N/A**	Not Indicated
Material Compatibility	Materials of construction are compatible with steam sterilization.	**Y**	Not Indicated

Toxicological Properties (Biocompatibility including sterilant residual limits	MEM Elution Cytotoxicity (ISO 10993-5) The test samples meet the USP and ISO 10993-5 requirements for this test. All controls were acceptable and the test considered valid. The test samples PASSED and are considered NON-CYTOTOXIC under the test conditions employed.	-	Not Indicated
Aeration Time	N/A	-	
Technical Characteristics	The technological characteristics of the subject devices are equivalent to the predicate devices. The cassettes / trays are made of standard medical grade materials and do not incorporate any new technological characteristics.	**Y**	Not Indicated
Sterilant Penetration Performance Data	The purpose of this study was to verify that the SteriZign Signatur Device Protection System allows for sufficient sterilant penetration when exposed to a pre-vacuum steam 132°C two (2) minute sterilization, half cycle with no BI growth.	**Y**	Not Indicated
Drying Time	30 minutes	**Y**	30 minutes

VIII. Conclusion

The subject device is substantially equivalent to the legally marketed predicate device.