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

May 29, 2015

Summit Medical Inc.
Ms. Nicole Dove
Quality Assurance/Regulatory Affairs Manager
815 Northwest Pkwy, Suite 100
St. Paul, MN 55121

Re: K142768
Trade/Device Name: Instru-Safe® Instrument Protection System
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: April 29, 2015
Received: May 1, 2015

Dear Ms. Dove:

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" (21CFR 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,

Tejashri Purohit-Sheth, M.D.

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

Erin I. Keith, M.S.
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)*
K142768

Device Name
Instru-Safe® Instrument Protection System

Indications for Use *(Describe)*
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 intended to allow sterilization of the enclosed medical devices during a Sterrad 100NX Flex Sterilization Cycle. The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with a legally marketed wrap or Aesculap rigid container. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in table 1.

Sterrad 100NX Flex Sterilization Cycle

Summit Cassette Model	Aesculap Container Model
IN-0000	*JM444
IN-6105	*JM440

*Validated by Summit Medical for use in Sterrad 100NX Flex Sterilization Cycle ONLY. Consult container instructions to ensure that contents do not exceed the sterilization containers intended load claims.

Lumen claims for Sterrad 100NX Flex Sterilization Cycle

Summit Cassette Model	Minimum Inside Diameter	Maximum Length	Number of Lumens	Wrap / Rigid Container
IN-0000	1 mm	850 mm	1	Wrap and Rigid Container
IN-8823	1 mm	850 mm	1	Wrap and Rigid Container
IN-7344	1 mm	850 mm	1	Wrap
IN-6105	4 mm	235 mm	1	Wrap and Rigid Container

The worst case validated load by vent-to-volume calculation is the IN-0000 tray.
Note: The IN-0000 tray is for testing purposes only.

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, including 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 OMB number."

Indications for Use Statement

Table 1 – Device Models

Part Number	Maximum # of Instruments	Estimated Weight - Tray w/ instruments (lbs)
IN-1315	30	3.5
IN-2840	36	8.75
IN-2842	24	6.5
IN-2843	36	8.75
IN-2880	56	12.1
IN-2900	22	4.18
IN-3030	34	9.5
IN-5401-12	12	3.25
IN-7120	45	11.25
IN-7130	45	13.5
IN-7223	10	9.2
IN-7344	1	4
IN-7723	15	7.18
IN-7724	15	7.2
IN-7725	10	9.5
IN-7940	20	13.25
IN-8240	20	13.5
IN-8610	2	6.65
IN-8612	2	6.8
IN-8613	2	6.1
IN-8620	3	7.2
IN-8621	4	7.18
IN-8622	4	7.18
IN-8630	3	6.5
IN-8632	3	6.45
IN-8633	3	6.8
IN-8810	20	13.5
IN-8820	15	8.75
IN-8823	45	14
IN-8830	15	8.75
IN-8833	45	14
IN-8840	20	13.75
IN-8850	15	8.75
IN-8853	45	14
IN-8882	16	12.1

Summit Medical, Inc. | 815 Northwest Parkway, Suite 100 | St. Paul, MN 55121 USA
phone: 651.789.3939 | fax: 651.789.3979
www.summitmedicalusa.com

IN-8884	4	5.35
IN-8886	6	12.1
IN-8889	6	12.1
IN-8892-01	12	12.1
IN-8893	9	7.5
IN-8894	5	16.1
IN-8898	10	10.25
IN-8899	7	6.5
IN-8902	22	17
IN-8903	15	13.25
IN-8904	22	17
IN-8907	7	12.5
IN-8937	16	14.5
IN-8938	8	12.5
IN-8939	10	11.6
IN-8942	11	10
IN-8943	1	2.7
IN-8944	6	4.7
IN-8980-01	20	9.5
IN-8982-01	17	9.5
IN-8983-01	16	9.5
IN-8984-01	15	9.5
IN-8986-S	2	6.5
IN-8987-S	2	6.5
IN-8988-S	2	6
IN-8989-S	2	6
IN-9999-160	6	12.1

Summit Medical, Inc. | 815 Northwest Parkway, Suite 100 | St. Paul, MN 55121 USA
phone: 651.789.3939 | **fax:** 651.789.3979
www.summitmedicalusa.com

510(k) Summary

Following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92

Submitter:	Summit Medical Inc. 815 Northwest Parkway, Suite 100 St. Paul, MN 55121 Tel: (651) 789-3939
ER Number:	3008719017
Contact Person:	Nicole Dove QA/RA Manager Tel: (651) 789-3921 ndove@summitmedicalusa.com
Date Prepared:	May 26, 2015
Subject Device:	Trade Name(s): Instru-Safe® Instrument Protection System Classification Name: Sterilization wrap containers, trays, cassettes & other accessory (21 CFR 880.6850 Common Name: Instrument Tray, Sterilization Tray, Sterilization Cassettes, Instrument Delivery System Device Class: Class II Device Code: KCT Panel: General Hospital
Predicate Device:	Tradename: Instru-Safe Instrument Protection System 510(k) Holder: Summit Medical Inc. 510(k) #: K133015
Device Description:	Summit Medical Inc. Instru-Safe Instrument 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 latchable cover. The cassettes / trays have perforations to allow sterilant penetration. The cassettes / trays contain silicone inserts in the base and/or cover to hold,

<table>
<tr><td></td><td colspan="2">organize and protect the surgical instruments within the cassette / tray.</td></tr>
<tr><td>Intended Use:</td><td colspan="2">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 intended to allow sterilization of the enclosed medical devices during a Sterrad 100NX Flex Sterilization Cycle. The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility. A full list of device models is provided in table 1.
Sterrad 100NX Flex Sterilization Cycle
<table>
<tr><td>Summit Cassette Model</td><td>Aesculap Container Model</td></tr>
<tr><td>IN-0000</td><td>*JM444</td></tr>
<tr><td>IN-6105</td><td>*JM440</td></tr>
</table>
*Validated by Summit Medical for use in Sterrad 100NX Flex Sterilization Cycle ONLY. Consult container instructions to ensure that contents do not exceed the sterilization containers intended load claims.

Lumen claims for Sterrad 100NX Flex Sterilization Cycle
<table>
<tr><td>Summit Cassette Model</td><td>Minimum Inside Diameter</td><td>Maximum Length</td><td>Number of Lumens</td><td>Wrap / Rigid Container</td></tr>
<tr><td>IN-0000</td><td>1 mm</td><td>850 mm</td><td>1</td><td>Wrap and Rigid Container</td></tr>
<tr><td>IN-8823</td><td>1 mm</td><td>850 mm</td><td>1</td><td>Wrap and Rigid Container</td></tr>
<tr><td>IN-7344</td><td>1 mm</td><td>850 mm</td><td>1</td><td>Wrap</td></tr>
<tr><td>IN-6105</td><td>4 mm</td><td>235 mm</td><td>1</td><td>Wrap and Rigid Container</td></tr>
</table>
The worst case validated load by vent-to-volume calculation is the IN-0000 tray.
Note: The IN-0000 tray is for testing purposes only.</td></tr>
<tr><td></td><td colspan="2">The intended use of the subject device includes the Sterrad 100NX Flex Sterilization Cycle. Performance testing has been performed for the Sterrad 100NX Flex Sterilization Cycle. This new sterilization cycle does not affect safety and effectiveness of the Instru-Safe Instrument Protection System.</td></tr>
<tr><td>Comparison of Characteristics to Predicate Device:</td><td colspan="2">Based on a comparison of the design, technology, materials, manufacturing, performance, specifications and methods of use, the Instru-Safe Instrument Protection System is equivalent to the identified 510(k) cleared predicate device.</td></tr>
<tr><td>Element</td><td>New Device</td><td>Predicate (K133015)</td></tr>
</table>

<table>
<tr>
<td>Intended Use</td>
<td>Instru-Safe Instrument Protection System cassettes used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe Instrument Protection System cassettes are intended to allow sterilization of the enclosed medical devices during a Sterrad 100NX Flex Sterilization Cycle. The Instru-Safe Instrument Protection System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. The Instru-Safe Instrument Protection System cassettes are not intended on their own to maintain sterility.
Sterilization methods and configurations
• Sterrad 100NX Flex Sterilization Cycle
<table>
<tr><th>Summit Cassette Model</th><th>Aesculap Container Model</th></tr>
<tr><td>IN-0000</td><td>*JM444</td></tr>
<tr><td>IN-6105</td><td>*JM440</td></tr>
</table>
*Validated by Summit Medical for use in Sterrad 100NX Flex Sterilization Cycle ONLY. Consult container instructions to ensure that contents do not exceed the sterilization containers intended load claims.</td>
<td>Instru-Safe Instrument Protection System cassettes are used to organize and protect other medical devices that are sterilized by a healthcare provider. Instru-Safe System cassettes are intended to allow sterilization of the enclosed medical devices during a pre-vacuum steam sterilization cycle. The Instru-Safe System cassettes are intended to be used in conjunction with legally marketed wrap or Aesculap rigid container. The Instru-Safe System cassettes are not intended on their own to maintain sterility.

Sterilization methods and configurations
• Autoclave Sterilization Parameter:
Cycle: Pre-vacuum
Temperature: 270ºF (132°C)
Exposure Time: 4 minutes
Minimum Dry Time: 30 minutes
<table>
<tr><th>Summit Cassette Model</th><th>Aesculap Container Model</th></tr>
<tr><td>IN-8823-AE</td><td>*JN444</td></tr>
<tr><td>IN-2880</td><td>*JK444</td></tr>
<tr><td>IN-6105</td><td>*JN742</td></tr>
</table>
*Validated by Summit Medical for use in steam prevacuum sterilizers ONLY operating at 270ºF (132°C) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization containers intended load claims.</td>
</tr>
<tr>
<td>Material Composition</td>
<td>No changes from predicate device</td>
<td>The cassette contains components made of anodized aluminum, stainless steel, blue silicone, black silicone, polyester, ultem™ 1000</td>
</tr>
<tr>
<td>Physical Properties</td>
<td>Instru-Safe Instrument Protection System cassettes include
- perforated base
- perforated cover</td>
<td>Instru-Safe Instrument Protection System cassettes include
- perforated base
- perforated cover</td>
</tr>
</table>

	- silicone inserts (hold-it / hold down) - Handles - Latches - Feet - Posts (optional) - Divider (optional) - Shelf (optional)	- silicone inserts (hold-it / hold down) - Handles - Latches - Feet - Posts (optional) - Divider (optional) - Shelf (optional)
Chemical Properties	Not Applicable	Not Applicable
Configurations/ Dimensions	Various configurations / dimensions	See table located in predicate device submission K133015
Air permeance	Not Applicable	Not Applicable
Percent of surface performations	Not Applicable	Not Applicable
Performance	New Device	Predicate (K133015)
Sterilant Penetration	Sterrad 100NX Flex Sterilization Cycle	Pre-Vacuum Steam Cycle: Pre-vacuum Temperature: 270ºF (132°C) Exposure Time: 4 minutes Minimum Dry Time: 30 minutes
Microbial Barrier Properties (Packaging Integrity)	Not Applicable	Not Applicable
Material Compatibility	No changes from predicate device	Refer to predicate device K133015
Toxicological Properties (Biocompatibility, including Sterilant Residue 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-TOXIC under the test conditions employed.	Refer to predicate device K133015
Shelf Life	No Change	Reusable (5 year accelerated shelf life study)
Drying Time	Not Applicable	Autoclave Sterilization Parameter: Cycle: Pre-Vacuum Temperature: 270°F (132°C) Minimum Exposure Time: 4 minutes

		Minimum Dry Time: 30 minutes
Aeration Time	Not Applicable	Not Applicable
Technological 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.	
Performance Data:	Sterilization validation testing was performed to demonstrate Instru-Safe Instrument Protection System compatibility when used in a Sterrad 100NX Flex Sterilization Cycle with a legally marketed wrap or Aesculap rigid container.	
Conclusion:	Based upon intended use, performance data and technical information provided in this pre-market notification, the Instru-Safe® Instrument Protection System described herein is substantially equivalent to the predicate device [Instru-Safe® Instrument Protection System (K133015)].	

Table 1 – Device Models

Part Number	Maximum # of Instruments	Estimated Weight - Tray w/ instruments (lbs)
IN-1315	30	3.5
IN-2840	36	8.75
IN-2842	24	6.5
IN-2843	36	8.75
IN-2880	56	12.1
IN-2900	22	4.18
IN-3030	34	9.5
IN-5401-12	12	3.25
IN-7120	45	11.25
IN-7130	45	13.5
IN-7223	10	9.2
IN-7344	1	4
IN-7723	15	7.18
IN-7724	15	7.2
IN-7725	10	9.5
IN-7940	20	13.25
IN-8240	20	13.5
IN-8610	2	6.65
IN-8612	2	6.8
IN-8613	2	6.1
IN-8620	3	7.2
IN-8621	4	7.18
IN-8622	4	7.18
IN-8630	3	6.5
IN-8632	3	6.45
IN-8633	3	6.8
IN-8810	20	13.5
IN-8820	15	8.75
IN-8823	45	14
IN-8830	15	8.75
IN-8833	45	14
IN-8840	20	13.75
IN-8850	15	8.75
IN-8853	45	14

IN-8882	16	12.1
IN-8884	4	5.35
IN-8886	6	12.1
IN-8889	6	12.1
IN-8892-01	12	12.1
IN-8893	9	7.5
IN-8894	5	16.1
IN-8898	10	10.25
IN-8899	7	6.5
IN-8902	22	17
IN-8903	15	13.25
IN-8904	22	17
IN-8907	7	12.5
IN-8937	16	14.5
IN-8938	8	12.5
IN-8939	10	11.6
IN-8942	11	10
IN-8943	1	2.7
IN-8944	6	4.7
IN-8980-01	20	9.5
IN-8982-01	17	9.5
IN-8983-01	16	9.5
IN-8984-01	15	9.5
IN-8986-S	2	6.5
IN-8987-S	2	6.5
IN-8988-S	2	6
IN-8989-S	2	6
IN-9999-160	6	12.1