



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 13, 2014

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

Re: K133015
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: February 12, 2014
Received: February 14, 2014

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.

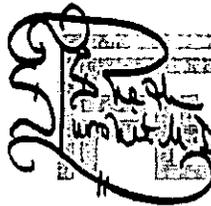
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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,


Tejasri Purohit Sheth, M.D.
Clinical Deputy Director
DAGRID

FOR

Erin I. Keith, M.S.
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 Statement

Page ____ of ____

510(k) number: Unknown, new submission - TBD K133015

Device Name: Instru-Safe® Instrument Protection System

Indications for Use:

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 pre-vacuum steam sterilization cycles. 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.

Autoclave Sterilization Parameter

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

Summit Cassette Model	Aesculap Container Model
IN-8823-AE	*JN444
IN-2880	*JK444
IN-6105	*JN742

*Validated by Summit Medical for use in steam prevacuum sterilizers ONLY operating at 270°F (132°C) for 4 minutes exposure time. Consult container instructions to ensure that contents do not exceed the sterilization containers intended load claims.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth F. Claverie -S

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Prescription Use: _____ OR Over-The-Counter X _____
(Per 21 CFR 801.109)



Indications for Use Statement

Page ____ of ____

Lumen size of instrumentation validated includes:

Summit Cassette Model	Minimum Inside Diameter	Maximum Length	Number of Lumens
IN-8823-CF	3mm	400mm	4
IN-8823-CF	3mm	200mm	2
IN-2880	1mm	76mm	2
IN-2880	3mm	177mm	1
IN-6105	5mm	241mm	1
IN-2681	1mm	65mm	1
IN-2681	3mm	200mm	1
IN-7823	1mm	400mm	17



Indications for Use Statement

Attachment 1 – Device Models

Part Number	Maximum # of Instruments	Estimated Weight - Tray w/ instruments (lbs)
IN-2681	13	0.64
IN-2682	13	0.89
IN-2683	13	1.39
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-2950	12	4.1
IN-3030	34	9.5
IN-4000	20	3.2
IN-4003	30	3.25
IN-4010	10	1.98
IN-5401	6	2
IN-5401-02	2	1
IN-5401-03	2	1
IN-5401-08	8	3.2
IN-5401-12	12	3.25
IN-6103	2	2.15
IN-6105	2	2.15
IN-6110	3	2.15
IN-6203	2	2.75
IN-6205	2	2.75
IN-6210	2	2.75
IN-6240	2	2.75
IN-6303	2	3.28
IN-6305	2	3.28
IN-6310	2	3.28
IN-6403	2	3.28
IN-6405	2	3.28
IN-6410	2	3.28
IN-7012	1	1.07
IN-7032	2	1.1
IN-7150	8	1.9
IN-7153	6	1.7



IN-7223	10	9.2
IN-7224	15	7.2
IN-7225	10	9.5
IN-7723	15	7.18
IN-7724	15	7.2
IN-7725	10	9.5
IN-7823	25	4
IN-7940	20	13.25
IN-8240	20	13.5
IN-8420	20	13.5
IN-8610	2	6.65
IN-8612	2	6.8
IN-8613	2	6.1
IN-8615	2	5.8
IN-8616	2	5.8
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-8640	4	5.35
IN-8642	4	5.35
IN-8643	5	5.35
IN-8645	4	5.35
IN-8660	4	5.35
IN-8662	4	5.35
IN-8663	4	5.35
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-8860	15	8.75
IN-8862	30	10.5

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IN-8863	45	14
IN-8880	2	3.28
IN-8882	16	12.1
IN-8883	2	3.28
IN-8884	4	5.35
IN-8885	1	2.25
IN-8886	6	12.1
IN-8889	6	12.1
IN-8891-S	1	2
IN-8891-SI-12-S	1	2
IN-8891-SI-85-S	1	2
IN-8892-01	12	12.1
IN-8893	9	7.5
IN-8894	5	16.1
IN-8897	8	6
IN-8898	10	10.25
IN-8899	7	6.5
IN-8901	1	2.25
IN-8902	22	17
IN-8903	15	13.25
IN-8904	22	17
IN-8907	7	12.5
IN-8945	2	5.18
IN-8946	9	6.1
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
IN-9999-162-S	2	5.8
IN-9999-168-S	2	5.8
IN-9999-172-S	2	5.8
IN-9999-178-S	2	5.8

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