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 1, 2014

Intuitive Surgical, Inc.
Mr. Brandon Hansen
Project Manager, Regulatory Affairs
1266 Kifer Road
Sunnyvale, CA 94086

Re: K133942
Trade/Device Name: Endoscope Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Tray
Regulatory Class: II
Product Code: KCT
Dated: July 8, 2014
Received: July 9, 2014

Dear Mr. Hansen:

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" (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 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,

Mary S. Runner -S

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)*
K133942

Device Name
Endoscope Sterilization Tray

Indications for Use *(Describe)*

The Intuitive Surgical Endoscope Sterilization Tray is intended for use to encase and protect da Vinci Xi endoscopes (Model #'s 470026 and 470027) for sterilization in the STERRAD 100NX sterilization system using the Express cycle and in the STERRAD 100S sterilization system using the standard cycle. The sterilization cycle parameters of the sterilizers are preset by the manufacturer and are not adjustable. The maximum product load per tray is 1 da Vinci Xi Endoscope. The max weight of tray and endoscope is 7.7 lbs.
The Intuitive Surgical Endoscope Sterilization Tray is intended to be used with legally marketed, FDA-cleared STERRAD compatible sterilization wrap in order to maintain sterility of the enclosed endoscope.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sreekanth Gutala -S

Digitally signed by Sreekanth Gutala -S
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Date: 2014.08.01 09:55:45 -04'00'

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510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Brandon Hansen Project Manager, Regulatory Affairs Phone Number: 408-523-7485 Fax Number: 408-523-8907 Email: Brandon.Hansen@intusurg.com
Date Summary Prepared:	July 9, 2014
Trade Name:	Endoscope Sterilization Tray
Common Name:	Sterilization Tray
Classification:	Class II 21 CFR 880.6850, Sterilization Wrap
Product Codes:	KCT
Classification Advisory Committee:	General Hospital
Predicate Device:	Entellus Medical FinESS Endoscope Sterilization Tray (K103213)

Device Description

The Endoscope Sterilization Tray is a thermoformed plastic tray with silicone inserts and a clear lid. The tray and lid contain perforations to allow sterilization gases to penetrate the tray and sterilize the endoscope. The Endoscope Sterilization Tray is designed to encase and protect *da Vinci* endoscopes during transport and sterilization. The tray is compatible with the STERRAD 100NX and 100S sterilization systems.

Intended Use:

To encase and protect *da Vinci* endoscopes for sterilization.

Indications for Use:

The Intuitive Surgical Endoscope Sterilization Tray is intended for use to encase and protect da Vinci Xi endoscopes (Model #'s 470026 and 470027) for sterilization in the STERRAD 100NX sterilization system using the Express cycle and in the STERRAD 100S sterilization system using the standard cycle. The sterilization cycle parameters of the sterilizers are preset by the manufacturer and are not adjustable. The maximum product load per tray is 1 da Vinci Xi Endoscope. The max weight of tray and endoscope is 7.7 lbs.
The Intuitive Surgical Endoscope Sterilization Tray is intended to be used with legally marketed, FDA-cleared STERRAD compatible sterilization wrap in order to maintain sterility of the enclosed endoscope.

Technological Characteristics:

The Intuitive Surgical Endoscope Sterilization Tray is substantially equivalent to the Entellus Medical FinESS Endoscope Sterilization Tray (K103213) in design, materials, technological characteristics, and intended use.

Characteristic	**Subject Device** Intuitive Surgical, Inc. Endoscope Sterilization Tray (K133942)	**Predicate Device** Entellus Medical FinESS™ Endoscope Sterilization Tray (K103213)
Manufacturer	Intuitive Surgical, Inc.	Entellus Medical, Inc.
Trade Name	Endoscope Sterilization Tray	FinESS™ Endoscope Sterilization Tray
510(k) No.	K133942	K103213
510(k) Decision Date	Not Applicable	2 February 2011

Characteristic	**Subject Device** Intuitive Surgical, Inc. Endoscope Sterilization Tray (K133942)	**Predicate Device** Entellus Medical FinESS™ Endoscope Sterilization Tray (K103213)
Common Name	Sterilization Tray	Identical
Regulation No.	21 CFR 880.6850	Identical
Product Code	KCT	Identical
Device Class/ Regulation Name	Class II/ Sterilization Wrap	Identical
Classification Advisory Committee	General Hospital	Identical
Sterilization Method	H_2O_2 chemical sterilization	Identical
Sterility / Disposable or Multiple use	Multiple use	Identical
Intended Use	Intended to encase and protect *da Vinci* endoscopes for sterilization in the STERRAD 100NX sterilization system using the express cycle setting and the 100S sterilization system using the standard cycle setting	Intended to encase and protect the FinESS™ Endoscope for sterilization in STERRAD 100NX using the standard cycle setting and NX sterilization system using the advanced cycle setting

Characteristic	**Subject Device** Intuitive Surgical, Inc. Endoscope Sterilization Tray (K133942)	**Predicate Device** Entellus Medical FinESS™ Endoscope Sterilization Tray (K103213)
Indications for Use	The Intuitive Surgical Endoscope Sterilization Tray is intended for use to encase and protect da Vinci Xi endoscopes (Model #'s 470026 and 470027) for sterilization in the STERRAD 100NX sterilization system using the Express cycle and in the STERRAD 100S sterilization system using the standard cycle. The sterilization cycle parameters of the sterilizers are preset by the manufacturer and are not adjustable. The maximum product load per tray is 1 da Vinci Xi Endoscope. The max weight of tray and endoscope is 7.7 lbs. The Intuitive Surgical Endoscope Sterilization Tray is intended to be used with legally marketed, FDA-cleared STERRAD compatible sterilization wrap in order to maintain sterility of the enclosed endoscope.	The FinESS™ Endoscope Sterilization Tray is intended for use to encase and protect the FinESS™ Endoscope for sterilization in STERRAD 100NX using the standard cycle setting and NX Sterilization Systems using the advanced cycle setting. • The sterilization cycle parameters of the STERRAD sterilizers are preset by the manufacturer and are not adjustable. • The maximum product load per FinESS™ Endoscope Sterilization Tray includes 1 FinESS™ Endoscope and 2 light post adapters. The FinESS™ Endoscope Sterilization Tray is intended to be used with legally marketed, FDA-cleared STERRAD compatible sterilization wrap in order to maintain sterility of the enclosed endoscope.
Where used (hospital, home, ambulance, etc)	Hospital	Identical
Dimensions (LxW)	25in. x 15in.	7.6 in. x 4.1 in.
Materials;	ULTEM™, Elastosil R401/70 Silicone, stainless steel	Identical

Characteristic	**Subject Device** Intuitive Surgical, Inc. Endoscope Sterilization Tray (K133942)	**Predicate Device** Entellus Medical FinESS™ Endoscope Sterilization Tray (K103213)
Compatibility with the environment and other devices	Compatible with *da Vinci* Xi 8 mm endoscopes	Compatible with the FinESS endoscope
Sterilization system compatibility	STERRAD 100NX and 100S	STERRAD 100NX and NX

Performance Data:

Performance test data (bench, cleaning, and sterilization tests) demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The testing conducted consisted of dimensional measurements, functional verification, and cleaning and sterilization testing.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the Intuitive Surgical Endoscope Sterilization Tray is substantially equivalent to the Entellus Medical FinESS Endoscope Sterilization Tray (K103213).