DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

February 24, 2015

Intuitive Surgical, Inc.
Ms. Nadine Nasr
Senior Regulatory Specialist, Regulatory Affairs
1266 Kifer Road
Sunnyvale, CA 94086

Re: K142937
Trade/Device Name: Endoscope Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap, Containers, Trays, Cassettes and Other Accessories
Regulatory Class: II
Product Code: KCT
Dated: January 26, 2015
Received: January 28, 2015

Dear Ms. Nasr:

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,

Tejashri Purohit-Sheth, M.D.

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

Erin I. Keith, M.S.
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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)*
K142937

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 any of the following sterilization machines/cycles:

- STERRAD 100NX sterilization system using the Express cycle
- STERRAD 100S sterilization system using the Standard cycle
- Steris V-PRO maX using the Non Lumen, Flexible, or Lumen cycles
- Steris V-PRO 1 Plus using the Non Lumen or Lumen cycles
- Steris V-PRO 1 using the V-PRO/Lumen cycle

The sterilization cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one da Vinci Xi Endoscope. The length of the da Vinci Xi Endoscope is approximately 600 mm and the diameter of the shaft is 8.8 mm. The maximum weight of tray and endoscope is 7.7 lbs.

The Endoscope Sterilization Tray is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared STERRAD and Steris compatible sterilization wrap in order to maintain sterility of the enclosed medical instrument.

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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510(k) Summary
K142937

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Nadine Nasr Senior Regulatory Specialist, Regulatory Affairs Phone Number: 408-523-7093 Fax Number: 408-523-8907 Email: Nadine.nasr@intusurg.com
Date Summary Prepared:	February 24, 2015
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:	Intuitive Surgical Endoscope Sterilization Tray (K133942)

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 Xi* endoscopes (Model #'s 470026 and 470027) during transport and sterilization. The tray is compatible with the STERRAD 100NX (Express cycle), STERRAD 100S (Standard cycle), and the following Steris low temperature hydrogen peroxide gas sterilization systems:

- Steris V-PRO maX using the Non Lumen, Flexible, or Lumen Cycles
- Steris V-PRO 1 Plus using the Non Lumen or Lumen Cycles
- Steris V-PRO 1 using the V-PRO/Lumen Cycle

The Endoscope Sterilization Tray is the same tray previously cleared for sterilizing the endoscopes in STERRAD sterilizers. The tray is now validated for use in the Steris sterilization systems and the Indications for Use are being modified to reflect that capability.

Intended 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 any of the following sterilization machines/cycles:

- STERRAD 100NX sterilization system using the Express cycle
- STERRAD 100S sterilization system using the Standard cycle
- Steris V-PRO maX using the Non Lumen, Flexible, or Lumen cycles
- Steris V-PRO 1 Plus using the Non Lumen or Lumen cycles
- Steris V-PRO 1 using the V-PRO/Lumen cycle

The sterilization cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one *da Vinci Xi* Endoscope. The length of the *da Vinci Xi* Endoscope is approximately 600 mm and the diameter of the shaft is 8.8 mm. The maximum weight of tray and endoscope is 7.7 lbs.

The Endoscope Sterilization Tray is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared STERRAD and Steris compatible sterilization wrap in order to maintain sterility of the enclosed medical instrument.

Technological Characteristics:

The subject Intuitive Surgical Endoscope Sterilization Tray is substantially equivalent to the predicate Intuitive Surgical Endoscope Sterilization Tray (K133942) in design, materials, and technological characteristics.

Characteristic	**Subject Device** Intuitive Surgical, Inc. Endoscope Sterilization Tray K142937	**Predicate Device** Intuitive Surgical, Inc. Endoscope Sterilization Tray K133942
Manufacturer	Intuitive Surgical, Inc.	Intuitive Surgical, Inc.
Trade Name	Endoscope Sterilization Tray	Endoscope Sterilization Tray
510(k) No.	K142937	K133942
510(k) Decision Date	Not Applicable	August 1, 2014
Common Name	Sterilization Tray	Sterilization Tray
Regulation No.	21 CFR 880.6850	21 CFR 880.6850
Product Code	KCT	KCT
Device Class/ Regulation Name	Class II/ Sterilization Wrap	Class II/ Sterilization Wrap
Classification Advisory Committee	General Hospital	General Hospital
Sterilization Method	SAME	H_2O_2 chemical sterilization
Sterility / Disposable or Multiple use	SAME	Multiple use

Characteristic	Subject Device Intuitive Surgical, Inc. Endoscope Sterilization Tray K142937	Predicate Device Intuitive Surgical, Inc. Endoscope Sterilization Tray K133942
Intended Use	The Intuitive Surgical Endoscope Sterilization Tray is intended to encase and protect *da Vinci* Xi endoscopes for sterilization in the STERRAD 100NX sterilization system using the Express cycle setting, the STERRAD 100S sterilization system using the Standard cycle setting, and the Steris low temperature hydrogen peroxide gas sterilization systems (V-PRO maX, V-PRO 1 Plus, and V-PRO 1).	Intended to encase and protect *da Vinci* endoscopes for sterilization in the STERRAD 100NX sterilization system using the Express cycle setting and the STERRAD 100S sterilization system using the Standard cycle setting.

Characteristic	Subject Device Intuitive Surgical, Inc. Endoscope Sterilization Tray K142937	Predicate Device Intuitive Surgical, Inc. Endoscope Sterilization Tray K133942
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 any of the following sterilization machines/cycles: • STERRAD 100NX sterilization system using the Express cycle • STERRAD 100S sterilization system using the Standard cycle • Steris V-PRO maX using the Non Lumen, Flexible, or Lumen cycles • Steris V-PRO 1 Plus using the Non Lumen or Lumen cycles • Steris V-PRO 1 using the V-PRO/Lumen Cycle The sterilization cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one *da Vinci Xi* Endoscope. The length of the *da Vinci Xi* Endoscope is approximately 600 mm and the diameter of the shaft is 8.8 mm. The maximum weight of tray and endoscope is 7.7 lbs. The Endoscope Sterilization Tray is not intended to maintain sterility; it is intended to be used in conjunction with a legally marketed, validated, FDA-cleared STERRAD and Steris compatible sterilization wrap in order to maintain sterility of the enclosed medical instrument.	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 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 maximum 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.

Characteristic	Subject Device Intuitive Surgical, Inc. Endoscope Sterilization Tray K142937	Predicate Device Intuitive Surgical, Inc. Endoscope Sterilization Tray K133942
Where used (hospital, home, ambulance, etc)	SAME	Hospital
Dimensions (LxW)	SAME	25in. x 15in.
Materials;	SAME	ULTEM™, Elastosil R401/70 silicone, stainless steel
Compatibility with the environment and other devices	SAME	Compatible with *da Vinci* Xi endoscopes
Sterilization system compatibility	STERRAD 100NX and STERRAD 100S and Steris V-PRO maX, V-PRO 1 Plus, and V-PRO 1 low temperature hydrogen peroxide gas sterilization systems	STERRAD 100NX and STERRAD 100S

Performance Data:

Performance test data demonstrates 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 sterilization validation and limits of reuse testing. Bench testing, including dimensional measurements, functional verification, cleaning, and biocompatibility testing were not repeated as the subject device design, materials and manufacturing processes are identical to the predicate device (Intuitive Surgical Endoscope Sterilization Tray, K133942).

Substantially Equivalent Conclusion:

Based on the intended use, indications for use, technological characteristics, performance data and nonclinical tests performed, the subject Intuitive Surgical Endoscope Sterilization Tray is substantially equivalent and is as safe and as effective, and performs at least as safely and as effectively as the legally marketed predicate device, Intuitive Surgical Endoscope Sterilization Tray (K133942), Class II (21 CFR 880.6850), Product code KCT.