DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 17, 2017

Intuitive Surgical, Inc.
Kunal Gunjal
Regulatory Affairs Specialist
1266 Kifer Road
Building 101
Sunnyvale, California 94086

Re: K170640
Trade/Device Name: Endoscope Sterilization Tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: Class II
Product Code: KCT
Dated: August 24, 2017
Received: August 25, 2017

Dear Kunal Gunjal:

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 (DICE) 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 Industry and Consumer Education (DICE) 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,

Tara A. Ryan -S
2017.09.17 18:52:36 -04'00'

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

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)*
K170640

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 the tray and endoscope is 8.9 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.

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.

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"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."

510(k) Summary (K170640)

IS4000 Endoscope Sterilization Tray

510(k) Owner	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact	Kunal Gunjal Regulatory Affairs Specialist, Regulatory Affairs Phone Number: 408-523-8017 Fax Number: 408-523-8907 Email: Kunal.Gunjal@intusurg.com
Date Summary Prepared	September 13, 2017
Trade Name	Endoscope Sterilization Tray
Common Name	Sterilization Tray
Classification and Regulation	Class II, 21 CFR 880.6850
Product Codes	KCT
Classification Advisory Committee:	General Hospital
Predicate Device	K151450

Device Description

IS4000 Endoscope Sterilization Tray

Trade Name	Endoscope Sterilization Tray
Device Description	The **Endoscope Sterilization Tray** is intended for use to encase and protect *da Vinci Xi* Endoscopes during the sterilization process. It is a thermoformed plastic tray with silicone inserts and a clear lid. The tray and the lid contain perforations to allow sterilization gases to penetrate the tray and sterilize the endoscope.

Technological Comparison Table (Endoscope Sterilization Tray)

Characteristic	**Subject Device** *Endoscope Sterilization Tray* K170640	**Predicate Device** *Endoscope Sterilization Tray* K151450
Manufacturer	Intuitive Surgical, Inc.	Intuitive Surgical, Inc.
Trade Name	Endoscope Sterilization Tray	**SAME** as subject device
Common Name	Sterilization Tray	**SAME** as subject device
Regulation No.	21 CFR 880.6850	**SAME** as subject device
Product Code	KCT	**SAME** as subject device
Device Class/ Regulation Name	Class II	**SAME** as subject device

Characteristic	**Subject Device** *Endoscope Sterilization Tray* K170640	**Predicate Device** *Endoscope Sterilization Tray* K151450
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 the tray and endoscope is 8.9 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.	**SAME** as subject device
Sterilization Method	H_2O_2 chemical sterilization	**SAME** as subject device
Reusable	Yes	**SAME** as subject device
Reprocessing Instructions	The following changes have been made to the Reprocessing instructions for the Endoscope Sterilization Tray, since the most recently cleared legally marketed device (K151450): - Re-organization of content and formatting - Remove or add warning and caution statements - Revise warning and caution statements - Reference to specific washer/disinfector models was removed (Removed the automated cleaning process) - Addition of parameter based thermal disinfection process	

Technological Characteristics:

The technological characteristics of the subject device are identical to the predicate device.

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 Cleaning Validation and Human Factors Validation. Design validation studies were not repeated as the subject device design, materials, and manufacturing processes are identical to the predicate device.

Summary:

Based on the intended use, indications for use, technological characteristics, performance data, and nonclinical tests performed, the subject device is substantially equivalent and is as safe, as effective, and performs as well as the legally marketed predicate device.