



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

January 12, 2016

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

Re: K151450  
Trade/Device Name: Endoscope Sterilization Tray  
Regulation Number: 21 CFR 880.6850  
Regulation Name: Sterilization Wrap  
Regulatory Class: Class II  
Product Code: KCT  
Dated: December 15, 2015  
Received: December 16, 2015

Dear Mr. 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 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 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

**Indications for Use**

510(k) Number (if known)  
K151450

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 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.\***

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](mailto: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."*

## 510(k) Summary

**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:** December 15, 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 (K142937)

---

## 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 subject Endoscope Sterilization Tray and predicate tray are identical in terms of design, materials, dimensions and weight. The purpose of this 510(k) is to update the Indications for Use to reflect that the tray can accommodate a heavier endoscope. The previous Indications for Use reflected that the tray could accommodate a maximum of 7.7 lbs for the combined weight of the endoscope and tray, while the Indications for Use in this 510(k) reflect that the tray can accommodate a maximum of 8.9 lbs for the combined weight of the endoscope and tray.

## 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.

## Technological Characteristics:

The subject Intuitive Surgical Endoscope Sterilization Tray is identical to the predicate Intuitive Surgical Endoscope Sterilization Tray (K142937) in design, materials and technological characteristics; it is the same tray.

Characteristic	Subject Device Intuitive Surgical, Inc. Endoscope Sterilization Tray	Predicate Device Intuitive Surgical, Inc. Endoscope Sterilization Tray K142937
Manufacturer	Intuitive Surgical, Inc.	Intuitive Surgical, Inc.
Trade Name	Endoscope Sterilization Tray	Endoscope Sterilization Tray
510(k) No.	K151450	K142937
510(k) Decision Date	Not Applicable	February 24, 2015
Common Name	Sterilization Tray	Sterilization Tray

<b>Characteristic</b>	<b>Subject Device</b> Intuitive Surgical, Inc. Endoscope Sterilization Tray	<b>Predicate Device</b> Intuitive Surgical, Inc. Endoscope Sterilization Tray K142937
<b>Regulation No.</b>	21 CFR 880.6850	21 CFR 880.6850
<b>Product Code</b>	KCT	KCT
<b>Device Class/ Regulation Name</b>	Class II/ Sterilization Wrap	Class II/ Sterilization Wrap
<b>Classification Advisory Committee</b>	General Hospital	General Hospital
<b>Sterilization Method</b>	SAME	H <sub>2</sub> O <sub>2</sub> chemical sterilization
<b>Sterility / Disposable or Multiple use</b>	SAME	Multiple use
<b>Intended Use</b>	SAME	The Intuitive Surgical Endoscope Sterilization Tray is intended to encase and protect <i>da Vinci</i> 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).

<b>Characteristic</b>	<b>Subject Device</b> Intuitive Surgical, Inc. Endoscope Sterilization Tray	<b>Predicate Device</b> Intuitive Surgical, Inc. Endoscope Sterilization Tray K142937
<b>Indications for Use</b>	<p>The Intuitive Surgical Endoscope Sterilization Tray is intended for use to encase and protect <i>da Vinci Xi</i> endoscopes (Model #'s 470026 and 470027) for sterilization in any of the following sterilization machines/cycles:</p> <ul style="list-style-type: none"> <li>• STERRAD 100NX sterilization system using the Express cycle</li> <li>• STERRAD 100S sterilization system using the Standard cycle</li> <li>• Steris V-PRO maX using the Non Lumen, Flexible, or Lumen cycles</li> <li>• Steris V-PRO 1 Plus using the Non Lumen or Lumen cycles</li> <li>• Steris V-PRO 1 using the V-PRO/Lumen Cycle</li> </ul> <p>The sterilization cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one <i>da Vinci Xi</i> Endoscope. The length of the <i>da Vinci Xi</i> Endoscope is approximately 600 mm and the diameter of the shaft is 8.8 mm. The maximum weight of tray and endoscope is 8.9 lbs.</p> <p>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.</p>	<p>The Intuitive Surgical Endoscope Sterilization Tray is intended for use to encase and protect <i>da Vinci Xi</i> endoscopes (Model #'s 470026 and 470027) for sterilization in any of the following sterilization machines/cycles:</p> <ul style="list-style-type: none"> <li>• STERRAD 100NX sterilization system using the Express cycle</li> <li>• STERRAD 100S sterilization system using the Standard cycle</li> <li>• Steris V-PRO maX using the Non Lumen, Flexible, or Lumen cycles</li> <li>• Steris V-PRO 1 Plus using the Non Lumen or Lumen cycles</li> <li>• Steris V-PRO 1 using the V-PRO/Lumen Cycle</li> </ul> <p>The sterilization cycle parameters of the sterilizers are preset by the manufacturers and are not adjustable. The maximum product load per tray is one <i>da Vinci Xi</i> Endoscope. The length of the <i>da Vinci Xi</i> 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.</p> <p>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.</p>
<b>Where used</b> (hospital, home, ambulance, etc)	SAME	Hospital
<b>Dimensions</b> <b>(LxW)</b>	SAME	25in. x 15in.

<b>Characteristic</b>	<b>Subject Device</b> Intuitive Surgical, Inc. Endoscope Sterilization Tray	<b>Predicate Device</b> Intuitive Surgical, Inc. Endoscope Sterilization Tray K142937
<b>Materials;</b>	SAME	ULTEM™, Elastosil R401/70 silicone, stainless steel
<b>Compatibility with the environment and other devices</b>	SAME	Compatible with <i>da Vinci</i> Xi endoscopes
<b>Sterilization system compatibility</b>	SAME	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

**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 bench testing, included verification testing for weight and functional specifications. Cleaning, biocompatibility, and limits of reuse testing were not repeated as the subject device design, materials, and manufacturing processes are identical to the predicate device (Intuitive Surgical Endoscope Sterilization Tray, K142937).

**Substantially Equivalent Conclusion:**

Based on the intended use, indications for use, technological characteristics, performance data and nonclinical tests performed, the subject device, Intuitive Surgical Endoscope Sterilization Tray (K151450) is substantially equivalent and is as safe, as effective, and performs as well as the legally marketed predicate device, Intuitive Surgical Endoscope Sterilization Tray (K142937), Class II (21 CFR 880.6850), Product code KCT.