DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 9, 2015

Intuitive Surgical Incorporated
Vishal Kanani
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K153126
Trade/Device Name: da Vinci Xi Hasson Cone
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: October 26, 2015
Received: October 29, 2015

Dear Mr. Kanani:

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,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K153126

Device Name
da Vinci Xi Hasson Cone

Indications for Use *(Describe)*
The da Vinci Xi Hasson Cone has applications in laparoscopic surgery to establish a port of entry for Intuitive Surgical da Vinci Xi EndoWrist Instruments, endoscopes, or compatible accessories.

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) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Vishal Kanani Sr. Regulatory Affairs Specialist Phone Number: 408-523-2035 Fax Number: 408-523-8907 Email: vishal.kanani@intusurg.com
Date Summary Prepared:	October 27, 2015
Trade Name:	*da Vinci Xi* Hasson Cone
Common Name:	Endoscope and Accessories
Classification:	Class II 21 CFR 876.1500, Endoscope and Accessories
Product Code:	GCJ
Classification Advisory Committee:	General and Plastic Surgery
Predicate Device:	Hybrid Trocar System (K101937)

Device Description:

The *da Vinci Xi* Hasson Cone is a cone-shaped device which is intended to be used in endoscopic surgery to anchor a port of entry (i.e., cannula) to the patient. During Hasson, or open, surgical techniques, the user places a Hasson Cone in the opening of the body wall. The cannula shaft is inserted into the cone, effectively increasing the diameter of the cannula to the contour of the incision made in the body wall.

The Hasson Cone will be offered in two sizes; 8 mm and 12 mm & Stapler.

Intended Use:

The *da Vinci Xi* Hasson Cone is intended to be used in laparoscopic surgery to anchor a port of entry (i.e., cannula) to the patient.

Indications for Use:

The da Vinci Xi Hasson Cone has applications in laparoscopic surgery to establish a port of entry for *Intuitive Surgical da Vinci Xi EndoWrist* Instruments, endoscopes, or compatible accessories.

Technological Characteristics:

The subject device, *da Vinci Xi* Hasson Cone, is technologically very similar to the predicate device, Aesculap 10 mm Stability Cone for Trocar Sleeve (cleared under K101937). It has the same intended use, same fundamental scientific technology, and similar technological characteristics as the predicate device.

Performance Data:

Performance data (bench and animal testing) demonstrate that the subject device is substantially equivalent to the predicate device and that the design output meets the design input requirements. The testing included dimensional measurements, mechanical and functional verification, simulated use in animal models, and human factors assessment.

Bench Testing:

The *da Vinci Xi* Hasson Cone, was subjected to a series of bench tests to evaluate performance and to demonstrate that the design outputs meet the input requirements. The design verification testing included:

- Physical Specifications
- Mechanical Requirements
- User Interface Requirements
- Functional Requirements

Animal Validation Testing:

Design Validation Testing was performed using animal and cadaveric models to evaluate the performance of the *da Vinci Xi* Hasson Cone in a simulated clinical setting. The testing summarized in this submission validated general, functional, use and misuse-related, and interaction (compatibility) requirements for the subject device.

Human Factors Evaluation:

As part of the Usability Engineering Process for the *da Vinci Xi* Hasson Cone, a Usability Risk Analysis was created to identify any new usability characteristics related to safety, as well as foreseeable hazards and hazardous situations. All risks were assessed as having "Tolerable" or "Broadly Acceptable" pre-mitigated risk profiles. As a result, no further usability testing was conducted to evaluate the safety and usability of the subject device.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the *da Vinci Xi* Hasson Cone is substantially equivalent to its predicate device.