May 31, 2018

Intuitive Surgical, Inc.
Gayle Perry
Sr. Regulatory Affairs Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K173415
Trade/Device Name: EndoWrist 5mm Thoracic Grasper
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: October 31, 2017
Received: November 1, 2017

Dear Gayle Perry:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173415

Device Name
EndoWrist 5mm Thoracic Grasper

Indications for Use *(Describe)*
The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pick-ups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use (except for transoral otolaryngology surgical procedures). It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

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

[As Required by 21 CFR 807.92(c)]

May 30, 2018

Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Official Contact: Gayle Perry
Sr. Regulatory Affairs Engineer
Ph: 408-523-7252
Fax: 408-523-1390

Trade Name: *EndoWrist*® 5mm Thoracic Grasper

Common Name: Endoscope and accessories

Classification: Endoscope and accessories, 21 CFR 876.1500, NAY

Predicate Device: Intuitive Surgical *EndoWrist*® 8mm Thoracic Grasper (K123329)

Device Description: The *EndoWrist* 5mm Thoracic Grasper is an endoscopic instrument for use with the Intuitive Surgical *da Vinci S* Surgical System (K050369) or *da Vinci* Si Surgical System (K081137). The instrument is designed for atraumatic grasping, manipulation and blunt dissection of tissue while fitting through a 5mm instrument cannula. The *EndoWrist* 5mm Thoracic Grasper is re-usable, provided non-sterile, and must be cleaned and sterilized using pre-vacuum autoclave before use. The instrument is programmed for a limited number of uses to ensure reliability and consistent performance. The sterilized instrument is connected to the manipulator arm of the da Vinci Surgical System and the distal tip and shaft of the instrument are inserted through a cannula placed through the body wall of the patient.

Intended Use:
Intended use of the IS2000/IS3000 *EndoWrist* instruments:
EndoWrist Instruments, including scissors, scalpels, forceps, needle drivers and electrocautery are intended for endoscopic manipulation of tissue, including: grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery and suturing.

Each individual instrument is intended to be used for a subset of uses listed in the overall intended use. The subset of the intended uses that applies to the *EndoWrist* 5mm Thoracic Grasper includes only those that are applicable to this instrument.

Intended use of the *EndoWrist* 5mm Thoracic Grasper:
The *EndoWrist* 5mm Thoracic Grasper is intended for endoscopic manipulation of tissue, including grasping, retraction, blunt dissection and approximation.

Indications for Use:

The Intuitive Surgical Endoscopic Instrument Control System is intended to assist in the accurate control of Intuitive Surgical Endoscopic Instruments including rigid endoscopes, blunt and sharp endoscopic dissectors, scissors, scalpels, ultrasonic shears, forceps/pickups, needle holders, endoscopic retractors, stabilizers, electrocautery and accessories for endoscopic manipulation of tissue, including grasping, cutting, blunt and sharp dissection, approximation, ligation, electrocautery, suturing, and delivery and placement of microwave and cryogenic ablation probes and accessories, during urologic surgical procedures, general laparoscopic surgical procedures, gynecologic laparoscopic surgical procedures, transoral otolaryngology surgical procedures restricted to benign and malignant tumors classified as TI and T2, and for benign base of tongue resection procedures, general thoracoscopic surgical procedures, and thoracoscopically assisted cardiotomy procedures. The system can also be employed with adjunctive mediastinotomy to perform coronary anastomosis during cardiac revascularization. The system is indicated for adult and pediatric use (except for transoral otolaryngology surgical procedures). It is intended to be used by trained physicians in an operating room environment in accordance with the representative, specific procedures set forth in the Professional Instructions for Use.

Technological Characteristics: The *EndoWrist* 5mm Thoracic Grasper is equivalent to the predicate device in terms of its indications for use, design, technology, and performance specifications.

The patient contacting materials used in the *EndoWrist* 5mm Thoracic Grasper are used in other instruments cleared under predicate K123329 except for the main shaft material. The main shaft consists of a stainless steel tube with a PEEK coating.

The shaft diameter and wrist architecture of the *EndoWrist* 5mm Thoracic Grasper are identical to other *EndoWrist* 5mm instruments. The instrument employs a “snake wrist” architecture to provide 4 degrees of freedom (wrist pitch, wrist yaw, roll and grip).

The grip design was modified from previously cleared instruments to optimize the instrument’s performance in atraumatic grasping and manipulation of soft tissues such as or comparable to pulmonary tissue and atraumatic blunt dissection around vessels and pulmonary structures.

Performance Data: The *EndoWrist* 5mm Thoracic Grasper was evaluated using bench testing and animal/cadaver testing to demonstrate that the design output meets the input requirements and the device performed as intended.

Design Verification (bench testing): The subject device, *EndoWrist* 5mm Thoracic Grasper, was subjected to a series of bench tests to evaluate performance and to demonstrate that the design outputs meet the design input requirements. The design verification testing included confirmation that the device meets the:

- Physical Specifications including:
  - Physical measurements
  - Compatibility with accessories
- Performance Requirements including:
  - Range of motion
  - Friction
  - Grip offset

The device main shaft PEEK coating was also tested for verification/reliability to evaluate its ability to meet the requirements/specifications throughout the intended life of the device.

- Reprocessing and abrasion testing were performed to ensure the main tube is able to function adequately for the expected life of the instrument.
- Testing was performed per IEC60601-2-2:2009-02, 5th edition, to ensure the PEEK coating retained its insulative properties throughout life.

Design Validation (animal/cadaver): The safety and efficacy of the instrument was assessed in a canine model (*in vivo*) and cadavers to evaluate applicable requirements through normal and expected worst case use. Representative tissue types were used, as appropriate, for evaluating applicable requirements. Design validation demonstrated that the design outputs fulfill the user needs and that the intended use has been met.

Testing included:

- Compatibility with accessories and system
- Range of motion, intuitive motion, lack of friction
- CO2 insufflation maintained
- Tissue manipulation and atraumatic blunt dissection of tissue
- Instrument retains performance throughout intended life

Reprocessing: The Intuitive Surgical *EndoWrist* 5mm Thoracic Grasper is a reusable instrument that is cleaned and sterilized using pre-vacuum autoclave by the sterile reprocessing department of a hospital prior to use according to the instructions provided by Intuitive Surgical.

Cleaning, low level thermal disinfection and sterilization validations were performed in accordance with FDA guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. Guidance for Industry and Food and Drug Administration Staff. Document Issued on March 17, 2015.

- The cleaning validation was performed to demonstrate the cleaning efficacy of the cleaning process with ultrasonic bath using pH neutral enzymatic detergent.
- Thermal disinfection validation was performed to demonstrate the efficacy of low level thermal disinfection based on temperature and time parameters in a washer-disinfector.
- Steam sterilization validation was performed to demonstrate a sterility assurance level of at least 10^{-6}.

Summary: Based on the intended use, technical characteristics, and performance data, the *EndoWrist* 5mm Thoracic Grasper is equivalent to the predicate device in terms of safety, effectiveness, and performance.