DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

February 6, 2017

Intuitive Surgical, Inc.
Ms. Melissa Gonzalez
Sr. Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K162973
Trade/Device Name: EndoWrist Suction Irrigator
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: December 16, 2016
Received: December 19, 2016

Dear Ms. Gonzalez:

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,

Jennifer R. Stevenson -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)*
K162973

Device Name
EndoWrist® Suction Irrigator

Indications for Use *(Describe)*
The EndoWrist® Suction Irrigator is designed to be used in conjunction with an Intuitive Surgical da Vinci Surgical System and compatible suction and irrigation sources and tubing sets for delivering fluid to the surgical site and for evacuation and aspiration of fluids. The instrument may also be used for retraction and blunt dissection of tissue.

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.

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510(k) Summary

[As Required by 21 CFR 807.92(c)]

October 24, 2016

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

Official Contact: Melissa S. Gonzalez
Sr. Regulatory Affairs Specialist
Ph: 408-523-8684
Fax: 408-523-1390

Trade Name: Intuitive Surgical ***EndoWrist***® Suction Irrigator

Common Name: System, surgical, computer controlled instrument

Classification: Endoscope and accessories, 21 CFR 876.1500, NAY

Predicate Device: Intuitive Surgical *EndoWrist*® One Suction/Irrigator (K110451)

Device Description: The ***EndoWrist***® Suction Irrigator is a single-use, disposable instrument developed for use with the *da Vinci* Surgical System. The instrument provides the surgeon with the ability to activate suction and irrigation directly from the surgeon console or by depressing buttons on the instrument. Activation from the surgeon console will be controlled through the foot pedals on the surgeon console. The suction and irrigation sources are supplied by conventional devices (suction - canister, hospital line, etc.; and irrigation - closet, compressed air, gravity flow, etc.) that are available in an operating room setting.

Intended Use:
The *EndoWrist*® Suction Irrigator is intended for use in all endoscopic surgical applications where the compatible *da Vinci* Surgical System is indicated.

Indications for Use:
The *EndoWrist*® Suction Irrigator is designed to be used in conjunction with an Intuitive Surgical *da Vinci* Surgical System and compatible suction and irrigation sources and tubing sets for delivering fluid to the surgical site and for evacuation and aspiration of fluids. The instrument may also be used for retraction and blunt dissection of tissue.

Technological Characteristics: The ***EndoWrist*®** Suction Irrigator is equivalent to the predicate device in terms of its indications for use, design, technology, and performance specifications. An overview of the device characteristics for the ***EndoWrist*®** Suction Irrigator is provided in **Table 1**.

Table 1: General Device Characteristics

Subject & Predicate Device(s):	K162973	K110451
General Device Characteristics		
Instrument Shaft OD	0.33”	Same
Shaft Lumen ID	0.17”	Same
Shaft Length	22.2”	17.1”
Tubing Length	13’	Same
Tubing ID/OD	0.25”/0.375”	Same
Irrigation Flow Rate	≥ 1.75 L/min	Same
Valve Function	Sliding Cylinders	Same
Tip Articulation	Pitch/Yaw	Same
Provided Sterile/Single Use	Yes	Same
Sterilization Method	EtO	Same

Performance Data: The ***EndoWrist*®** Suction Irrigator was evaluated using bench testing and clinical models (animals/cadavers) to demonstrate that the design output meets the input requirements and the device performed as intended.

Design Verification (bench testing): The subject device, ***EndoWrist*®** Suction Irrigator, was subjected to series of bench tests to evaluate performance and to demonstrate that the design outputs meet the design input requirements. Testing was performed with a *da Vinci Xi* Surgical System (Model IS4000). The design verification testing included confirmation that the device meets the:

- Physical Specifications
- Mechanical Requirements
- Electrical Requirements
- User Interface Requirements
- Equipment Interface Requirements

Design Validation (animal/cadaver): The safety and efficacy of the instruments was assessed in representative simulated clinical settings that utilized porcine models (*in vivo*) and cadavers to evaluate applicable requirements through normal and expected worst case clinical 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.

Summary: Based on the intended use, technical characteristics, and performance data, the ***EndoWrist***® Suction Irrigator is equivalent to the predicate device in terms of safety, effectiveness, and performance.