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

April 21, 2017

Intuitive Surgical, Inc.
Ms. Cheryl Wu
Regulatory Affairs Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K170865
Trade/Device Name: EndoWrist Vessel Sealer, 8 mm Harmonic ACE Curved Shears, da Vinci Single-Site Instruments and Accessories
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: Class II
Product Code: NAY
Dated: March 21, 2017
Received: March 23, 2017

Dear Ms. Wu:

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

4.0 INDICATIONS FOR USE STATEMENT

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)*
K170865

Device Name
EndoWrist® Vessel Sealer

Indications for Use *(Describe)*
The EndoWrist Vessel Sealer is a bipolar electrosurgical instrument for use with a compatible da Vinci Surgical System and the ERBE VIO dV electrosurgical generator. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. The EndoWrist Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

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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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:

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Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

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FORM FDA 3881 (8/14) Page 1 of 1 PSC Publishing Services (301) 443-6740 EF

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)*
K170865

Device Name
8 mm Harmonic ACE® Curved Shears

Indications for Use *(Describe)*
The 8 mm Harmonic ACE Curved Shears is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with a compatible da Vinci Surgical System and a compatible Ethicon Endo-Surgery Generator and Hand Piece.

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)

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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)*
K170865

Device Name
da Vinci® Single-Site® Instruments and Accessories

Indications for Use *(Describe)*
The Intuitive Surgical da Vinci Single-Site Instruments and Accessories used with a compatible da Vinci Surgical System are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, suction/irrigation and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the da Vinci Single-Site Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, clip appliers, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, 8 mm endoscope cannula, flexible and rigid blunt obturators, cannula seal, and the Single-Site Port.

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)

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510(k) Summary

510(k) Submitter: Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact: Cheryl Wu
Regulatory Affairs Engineer
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Date Summary Prepared: March 21, 2016

Trade Name: *EndoWrist*® Vessel Sealer,
8 mm Harmonic ACE® Curved Shears,
da Vinci® *Single-Site*® Instruments and Accessories

Common Name: Endoscope and accessories

Classification: Class II
21 CFR 876.1500, Endoscope and Accessories

Product Codes: NAY

Classification Advisory Committee: General and Plastic Surgery

Predicate Device: K140189 – *EndoWrist* Vessel Sealer
K143132 – IS4000 8 mm Harmonic ACE Curved Shears
K152448 – *da Vinci Single-Site* Instruments and Accessories

Technological Characteristics:

The purpose of this submission is to change the Indications for Use for the *EndoWrist* Vessel Sealer, 8 mm Harmonic ACE Curved Shears, and *da Vinci Single-Site* Instruments and Accessories.

Specific references to compatible systems (i.e. "*Xi*", "Model IS4000") have been removed from the *EndoWrist* Vessel Sealer, 8 mm Harmonic ACE Curved Shears, and Single-Site Instruments and Accessories Indications for Use statements. The reference to "compatible *da Vinci* Surgical Systems" in the subject Indications for Use coupled with identification of specific systems compatibility in the Compatibility Information or Device Description section of the User Manual for the subject devices is essentially equivalent to the reference to model "IS4000" in the predicate Indications for Use statements.

The subject devices are identical to their predicate devices in terms of design, technology, and performance specifications. The Indications for Use and Device Description for the subject devices included in this submission are summarized below:

EndoWrist **Vessel Sealer**

Intended Use/Indications for Use

The *EndoWrist* Vessel Sealer is a bipolar electrosurgical instrument for use with a compatible *da Vinci* Surgical System and the ERBE VIO dV electrosurgical generator. It is intended for grasping and blunt dissection of tissue and for bipolar coagulation and mechanical transection of vessels up to 7 mm in diameter and tissue bundles that fit in the jaws of the instrument. The *EndoWrist* Vessel Sealer has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Device Description

The *EndoWrist* Vessel Sealer is a sterile, single-use (disposable), 8 mm instrument with an integrated cord that connects to the instrument housing and an Erbe VIO dV generator. The *EndoWrist* Vessel Sealer device consists of a distal wristed end effector and a proximal housing connected by a tubular shaft. The housing contains mechanisms to actuate the end effector when attached to a compatible *da Vinci* Surgical System. An integrated cord attached to the housing is connected to a receptacle in the IESU. An electrode sealing surface and a cutting blade within the jaws of the instrument enable sealing of vessels and cutting of sealed vessels and other tissues. The sealing and cutting functions are controlled using the compatible *da Vinci* Surgical System foot pedals.

8 mm Harmonic ACE Curved Shears

Intended Use/Indications for Use

The 8 mm Harmonic ACE Curved Shears is intended for soft tissue incisions when bleeding control and minimal thermal injury are desired. It is designed to be used in conjunction with a compatible *da Vinci* Surgical System and a compatible Ethicon Endo-Surgery Generator and Hand Piece.

Device Description

The *da Vinci* 8 mm Harmonic ACE Curved Shears is a single-use, sterile instrument used to deliver ultrasonic energy to enable transection and coagulation of tissue. The movement and function of the *da Vinci* 8 mm Harmonic ACE Curved Shears are controlled by the surgeon from the Surgeon Console of a compatible da Vinci Surgical System. This instrument consists of a housing, instrument shaft, and instrument jaws comprised of a clamp arm and blade.

***da Vinci Single-Site* Instruments and Accessories**

Intended Use/Indications for Use

The Intuitive Surgical *da Vinci Single-Site* Instruments and Accessories used with a compatible *da Vinci* Surgical System are indicated for use by trained physicians in an operating room environment for endoscopic manipulation of tissue, grasping, cutting, blunt and sharp dissection, approximation, clip-ligation, electrocautery, suction/irrigation and suturing during single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo-oophorectomy with the *da Vinci Single-Site* Instruments and Accessories, including graspers, dissectors, needle drivers, scissors, suction irrigators, monopolar cautery, bipolar cautery, clip appliers, 5 mm curved cannulae, 5 mm and 10 mm straight cannulae, 8 mm endoscope cannula, flexible and rigid blunt obturators, cannula seal, and the Single-Site Port.

Device Description

The *da Vinci Single-Site* Instruments and Accessories are a set of devices developed by Intuitive Surgical to enable single incision laparoscopic cholecystectomy, benign hysterectomy and salpingo oophorectomy using the compatible *da Vinci* Surgical System.

Performance Data:

In accordance with the Design Control process, risk analysis was conducted to evaluate the impact of labeling modifications on the predicate devices**.** Design verification and validation testing were not required since design inputs were not changed.

Summary:

Based on the intended use, indications for use, technological characteristics, and performance data, the subject devices are substantially equivalent to currently marketed predicate devices.