April 26, 2018

Intuitive Surgical, Inc.
Crystal Ong
Sr. Regulatory Engineer
1266 Kifer Road
Sunnyvale, California 94086

Re: K173337
Trade/Device Name: Intuitive Surgical EndoWrist Vessel Sealer Extend
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: April 9, 2018
Received: April 10, 2018

Dear Crystal Ong:

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)*

K173337

Device Name

EndoWrist Vessel Sealer Extend

Indications for Use *(Describe)*

The EndoWrist Vessel Sealer Extend 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 Extend 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.

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510(k) Summary

[As Required by 21 CFR 807.92(c)]

December 8, 2017

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

Official Contact: Crystal Ong
Sr. Regulatory Engineer
Ph: 408-523-8636
Fax: 408-523-8907

Trade Name: Intuitive Surgical *EndoWrist*® Vessel Sealer Extend

Common Name: System, surgical, computer controlled instrument

Classification: Endoscope and accessories, 21 CFR 876.1500, NAY

Predicate Device: Intuitive Surgical *EndoWrist*® Vessel Sealer (K170865)

Device Description: The *EndoWrist* Vessel Sealer Extend 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 Extend 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.

Intended Use:
The *EndoWrist* Vessel Sealer Extend 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 Extend has not been shown to be effective for tubal

sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

Technological Characteristics: The *EndoWrist*® Vessel Sealer Extend is equivalent to the predicate device in terms of its indications for use, design, technology, and performance specifications. Modifications from the predicate include a change in material and location of electrode spacers on the end effector (jaw). The changes to the instrument tip do not substantively change the function of the subject device relative to the function of the predicate device.

Performance Data: The *EndoWrist*® Vessel Sealer Extend was evaluated using bench testing, clinical models (animals/cadavers) and a chronic animal study (in-vivo, animal) to demonstrate that the design output meets the input requirements and the device performed as intended.

Design Verification (bench testing): The subject device, *EndoWrist*® Vessel Sealer Extend, 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 compatible *da Vinci s*urgical system. 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, including indicated vessel sizes, have been met.

Chronic Animal Study (animal): A chronic animal study was performed to evaluate the clinical performance (long-term seal quality) of the subject device *EndoWrist* Vessel Sealer Extend as compared to the predicate device, *EndoWrist* Vessel Sealer. This study allowed for the clinical assessment of vascular seal performance and the vascular healing response in a live animal model with similar human tissue characteristics and a similar abdominal cavity.

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