December 11, 2018

Intuitive Surgical, Inc.
Mr. Kunal Gunjal
Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K183107
Trade/Device Name: Intuitive Surgical Vessel Sealer Extend
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: November 7, 2018
Received: November 8, 2018

Dear Mr. Gunjal:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 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)*

K183107

Device Name

Intuitive Surgical Vessel Sealer Extend

Indications for Use *(Describe)*

Vessel Sealer Extend is a bipolar electrosurgical instrument for use with a compatible da Vinci Surgical System and a compatible 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. 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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7 510(k) Summary

510(k) Owner:	Intuitive Surgical, Inc. 1266 Kifer Road Sunnyvale, CA 94086
Contact:	Kunal Gunjal Regulatory Affairs Specialist Phone Number: 408-523-8017 Fax Number: 408-523-8907 Email: Kunal.Gunjal@intusurg.com
Date Summary Prepared:	November 7, 2018
Trade Name:	Intuitive Surgical 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 Extend (K173337)

Device Description: The 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 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.

Modifications from the predicate include a labeling change to remove references to using a specific electrosurgical generator (ERBE VIO dV electrosurgical generator) from the Indications for Use Statement that is listed as compatible with the Vessel Sealer Extend instrument. Additionally, *"EndoWrist"*, has been removed from the Indications for Use for product branding reasons.

Indications for Use:

Vessel Sealer Extend is a bipolar electrosurgical instrument for use with a compatible *da Vinci* Surgical System and a compatible 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. 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 subject Intuitive Surgical Vessel Sealer Extend is very similar to its predicate device originally cleared under K173337 for use with the *da Vinci Xi* system and *da Vinci X* system. It has the same intended use, same fundamental scientific technology, and similar technological characteristics as the predicate device.

Performance Data:

There were no design changes made to the subject Vessel Sealer Extend instrument as a result of the labeling change. Thus, the previously submitted bench testing reports and explanations demonstrating that the cleared predicate device (K173337) meet design specifications and performance requirements, apply to the subject device.

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