June 13, 2025

Intuitive Surgical, Inc.
Meirav Harsat
Regulatory Affairs Lead
1266 Kifer Road
Sunnyvale, California 94086

Re: K250674
Trade/Device Name: Vessel Sealer Curved (480522)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY
Dated: [NOTE: Use date of most recent supplement]
Received: May 15, 2025

Dear Meirav Harsat:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-

assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2025.06.13 07:55:49 -04'00'

Mark Trumbore Ph.D.
Assistant Director, THT4A1: Robotically-Assisted Surgical Devices Team
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K250674

Device Name

Vessel Sealer Curved (480522)

Indications for Use *(Describe)*

The Vessel Sealer Curved 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 blood vessels (veins and arteries) up to 7 mm in diameter, lymphatic vessels, and tissue bundles that fit in the jaws of the instrument. The Vessel Sealer Curved 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.

510(k) Summary

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

Official Contact: Meirav Harsat
Regulatory affairs Lead
Phone number: 650-862-4942
Email: Meirav.harsat@intusurg.com

Date Prepared: March 4, 2025

I. Subject Device:

Trade Name: Vessel Sealer Curved
Common Name: System, surgical, computer controlled instrument
Classification: Class II, Endoscope and accessories, 21 CFR 876.1500, NAY

II. Predicate Device:

Vessel Sealer Extend K183107

III. Device Description:

The Vessel Sealer Curved is a sterile, single-use (disposable), 8 mm instrument with an integrated cord that connects to the instrument housing. The Vessel Sealer Curved 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 Intuitive Electrosurgical generator, E-200. 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.

IV. Indications for Use:

The Vessel Sealer Curved 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 blood vessels (veins and arteries) up to 7 mm in diameter, lymphatic vessels, and tissue bundles that fit in the jaws of the instrument. The Vessel Sealer Curved has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures, and should not be used for these procedures.

V. Comparison of Technological Characteristics:

The Vessel Sealer Curved has the same intended use and fundamental scientific technology as its predicate device. It is similar to its predicate device in terms of its indication for use and technological characteristics. Differences between the predicate and the subject device include the addition of specific vessels to the indication for use, changes in design and materials at the end effector (jaw), and modifications to the electrical cable at the distal end. These changes do not substantively change the safety and performance of the subject device relative to the function of the predicate device.

VI. Performance Data:

Testing was performed with a compatible da Vinci surgical systems and Generator. Testing included design verification, compatibility verification, transit and shelf-life verification, biocompatibility, and design validation. The successful completion of testing demonstrated that the Vessel Sealer subject design outputs meets design inputs.

Design Verification

Bench testing was performed to verify that functional design outputs met the functional design inputs. The design verification in this section addressed the following

- Mechanical bench testing
- Reliability Testing
- Force to Jaw Failure
- Software Verification
- Testing in accordance with IEC60601-1 and IEC60601-1-2
- Usability Testing

Shelf-Life Verification

Device shelf-life verification testing was performed in accordance with ASTM F1980 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.

Transit Verification

Transit testing was performed in accordance with ASTM D4169-16, Standard Practice for Performance Testing of Shipping Containers and Systems.

Biocompatibility

Biocompatibility testing was completed in accordance with the following standards and guidance documents:

- FDA Guidance: Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process", issued September 2020
- ISO 10993-1:2018 Biological evaluation of medical devices

Design Validation

Animal testing was performed to validate that the product specifications meet the user's needs and intended use. These included:

- Design Validation
- Burst Pressure Testing
- Thermal Spread on Vessels
- Chronic Animal Study

VII. Conclusions:

Based on the intended use, technological characteristics, and performance data, the subject Vessel Sealer Curved is substantially equivalent to the Vessel Sealer Extend predicate device.