June 21, 2023

Intuitive Surgical
Shamsa Karimi
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K231212
Trade/Device Name: da Vinci E-200 Electrosurgical Generator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: April 27, 2023
Received: April 28, 2023

Dear Shamsa Karimi:

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/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 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 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: 2023.06.21 13:46:49 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
da Vinci E-200 Electrosurgical Generator

Indications for Use *(Describe)*
The da Vinci E-200 Electrosurgical Generator is intended to deliver high-frequency energy for cutting, coagulation and vessel sealing of tissues in da Vinci robotic procedures, and non-robotic open and laparoscopic 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

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

Official Contact: Shamsa Karimi
Sr. Regulatory Affairs Specialist
Phone Number: 408-806-6720
Fax Number: 408-523-8907
Email: shamsa.karimi@intusurg.com

Date Summary Prepared: April 27, 2023

Trade Name: da Vinci E-200 Electrosurgical Generator

Common Name: Electrosurgical Unit (ESU/Generator)

Classification: II
21 CFR 878.4400, Electrosurgical cutting and coagulation device and accessories.

Product Code: GEI (Electrosurgical, Cutting & Coagulation & Accessories)

Predicate Device: da Vinci E-200 Electrosurgical Generator (K223039)

Reference Device: Valleylab™ FT-10 Energy Platform (K151649)

Device Description:

The da Vinci E-200 is an electrosurgical unit (ESU) designed to provide high-frequency (HF) traditional monopolar, bipolar, and advanced bipolar outputs intended for cutting, coagulation and/or vessel sealing of tissues. The da Vinci E-200 is intended to be used with the IS4000/IS4200 da Vinci surgical systems, and also operate as a standalone electrosurgical generator. When connected to the da Vinci surgical system, the E-200 provides HF output to da Vinci instruments. Control and status messages are passed between the E-200 and the da Vinci system through an Ethernet communication cable. The E-200 is also compatible with open and laparoscopic third-party handheld monopolar and bipolar instruments, fingerswitch equipped

instruments (where applicable) and Intuitive provided auxiliary footswitches. The primary function of the E-200 Electrosurgical Generator is to allow a surgeon to deliver HF output to cut, seal, or coagulate tissue during surgery. The user interface includes audible indicator tones, LED indicators on the front of the generator, and status messages provided on its LCD display.

Intended Use/Indications for Use:

The da Vinci E-200 Electrosurgical Generator is intended to deliver high-frequency energy for cutting, coagulation and vessel sealing of tissues in da Vinci robotic procedures, and non-robotic open and laparoscopic procedures.

Technological Characteristics:

The technological characteristics of the subject E-200 Electrosurgical Generator are the same as the predicate device, da Vinci E-200 Electrosurgical Generator. Both are full featured electrosurgical generator and energy modes include traditional monopolar and bipolar and advanced bipolar energy modes. The E-200 provides the following incremental improvements while maintaining the same basic functionality and intended use.

- A new monopolar coagulation output mode, called “Low” is included to increase the range of behaviors for the E-200 monopolar coagulation output. A mode similar to this is available in other electrosurgical generators such as, SoftCoag mode in the Valleylab™ FT-10 Energy Platform.
- The rating of the Applied Parts is enhanced from Type CF to Defibrillation Proof Type CF
- Compatibility with an additional neutral electrode pad (Erbe, Nessy Monitoring Split pad) has been demonstrated.

Performance Data:

Verification and validation activities were successfully completed that establish that the E-200 Electrosurgical Generator performs as intended and is substantially equivalent to its predicate, da Vinci E-200 Electrosurgical Generator. Testing included the following:

Design Verification (bench testing):

The subject E-200 Electrosurgical Generator was subjected to a series of tests to evaluate performance and to demonstrate that the design outputs meet the design input requirements. The

design verification testing provided confirmation that the device meets the requirements for the following:

- Hardware requirements
- EMC and Electrical Safety requirements
- Software requirements including Cybersecurity
- System interface requirements
- Instrument compatibility requirements
- Packaging and Labeling

Design Validation*; In-vivo* testing with a porcine model was used to evaluate the safety and efficacy of the subject E-200 generator, and included utilization of its accessories (auxiliary footswitches and power cord), compatible robotic system(s), da Vinci and third-party instrument(s) and accessories in a representative simulated surgical setting. Design validation activities demonstrated that the design outputs fulfill the user needs and that the intended use have been met.

Thermal effects testing demonstrated the ability of the subject E-200 generator monopolar "Low" coagulation mode to create comparable thermal effects on tissue to the Soft Coag of Valleylab FT-10 Energy Platform (K151649), the reference device.

A neutral electrode contact quality monitor (CQM) study demonstrated conformance of the CQM system on the subject E-200 generator when used with the Erbe Nessy Monitoring Split pad (20193-074) to IEC 60601-2-2:2017. The study validated the compatibility of the Erbe, Nessy Monitoring Split pad neutral electrode (commercially available product) with the E-200 generator.

An evaluation of the capacitive coupling behavior of the E-200 generator performed using third party laparoscopic monopolar accessories demonstrated that the E-200 generator had no increase in unintended capacitively coupled energy delivery when compared to the predicate da Vinci E-200 Electrosurgical Generator.

The human factors evaluation determined that the subject E-200 ESU with its accessories in integrated, backup, and standalone setup configurations is safe and effective for its intended uses by the intended users, in the intended use environment.

Summary:

The evaluation of the proposed E-200 Electrosurgical Generator raises no new questions of safety or effectiveness and demonstrates that the E-200 design outputs meet the design input requirements and user needs and is substantially equivalent to the predicate device, da Vinci E-200 Electrosurgical Generator (K223039).