November 28, 2022

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

Re: K223039
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: September 28, 2022
Received: September 29, 2022

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,

Zhijie Liao -S

Digitally signed by Zhijie Liao -S
Date: 2022.11.28 14:53:05 -05'00'

For Mark Trumbore, PhD
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)*
K223039

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.

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510(k) Summary
(K223039)

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: November 23, 2022

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 Devices: Covidien ForceTRIAD Electrosurgical Generator (K110268, primary)
Intuitive E-100 Electrosurgical Generator (K191280, secondary)

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 human 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 Energy modes supported by E-200 include traditional monopolar and bipolar as well as advanced bipolar energy modes as described below.

Monopolar Energy Modes

The generator provides five monopolar modes to support a range of tissue effects, which can be used with compatible monopolar da Vinci instruments or compatible third-party instruments. Descriptions of the generator monopolar energy modes are listed below. The power settings for all monopolar modes can be adjusted from 0-120 watts.

- **Monopolar Cut Modes**

  Pure: provides clean, precise tissue division with little or no hemostasis.
  Blend: is a blended waveform that provides tissue division properties with some hemostasis.

- **Monopolar Coagulation Modes**

  Precise: provides a balance of hemostasis and division capability for precise coagulation energy applications. The width of the tissue effect can be narrower than Fulgurate mode.
  Fulgurate: provides coagulation with some tissue division.
  Spray: provides coagulation with limited tissue division properties. The width of the tissue effect can be wider compared to Fulgurate mode.

Bipolar Energy Modes

The generator produces four traditional bipolar modes to support a range of tissue effects, which can be used with compatible bipolar da Vinci instruments or compatible third-party instruments. Descriptions of the bipolar energy modes are listed below. The power settings for bipolar energy can be adjusted from 0-95 watts.

- **Bipolar modes**

  Macro: provides high intensity output for tissue division or rapid hemostasis.
  Standard: provides moderate intensity output for traditional bipolar application.
  Low: provides low intensity output for precise control over tissue desiccation.
  Low with Auto Stop: provides the same bipolar output as Low and automatically stops delivering bipolar radio frequency (RF) energy based on a pre-determined threshold. Low with Auto Stop is designed to reduce the potential for excessive thermal effect.

Advanced Bipolar Energy Modes

Advanced bipolar energy modes are designed for specific advanced energy instruments, and the algorithms used on the E-200 were developed to functionally replicate those used on the predicate device, the E-100 generator. Like the predicate device, the E-200 generator delivers two bipolar advanced energy modes for sealing and transection of vessels and tissue bundles, and also provides a traditional bipolar coagulation mode that can be used for general hemostasis without vessel sealing. Advanced energy modes are compatible only with da Vinci advanced energy instruments; SynchroSeal (K191280) and Vessel Sealer Extend (K183107).

- **Advanced Bipolar Modes**

  Coagulation Mode: It is a traditional bipolar mode used for general tissue coagulation and has a fixed target output power of 50 W.
  Sealing Mode: It is designed to seal vessels and tissue bundles when used with the da Vinci Vessel Sealer Extend and SynchroSeal. The generator determines when the seal cycle is complete thereby delivering the required amount of energy necessary to successfully seal vessels.
  Sync Mode: It is specifically designed for use with SynchroSeal for single-step sealing and transection of vessels and tissue bundles. The Sync mode uses a unique algorithm to control the energy output delivery to the seal and cut electrodes on the instrument. The generator automatically determines when the Sync mode cycle is complete, resulting in a single-step hemostatic transection of vessels and soft tissue.

Performance Data:

The E-200 Electrosurgical Generator was evaluated using design verification (bench testing), human factors testing, packaging(includes transit testing), and validated using in-vivo and ex-vivo models to demonstrate that the design output meets both the design input requirements and the user needs, and the generator performs as intended.

Design Verification (bench testing):

The subject device, E-200 Electrosurgical Generator, was subjected to 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 E-200 generator, its accessories and its interaction with intended robotic systems, da Vinci and third-party instruments and accessories in a representative simulated surgical setting. Design validation demonstrated that the design outputs fulfill the user needs and that the intended use have been met.

Thermal effects testing was conducted to demonstrate the ability of the subject E-200 generator to create comparable thermal effects on tissue to the predicate ForceTRIAD generator (K110268), the primary predicate. The E-200 generator was found to have acceptable thermal effects when compared to the ForceTRIAD generator.

Neutral electrode contact quality monitor (CQM) study was conducted to evaluate the performance of the CQM system on the subject E-200 generator for conformance to the IEC standards. The study validated the use of the Covidien E7507 neutral electrode (commercially available product) with the E-200 generator for CQM functionality.

The E-200/E-100 vessel sealing bench testing compared the HF output characteristics of the E-200 to the predicate E-100 device (K191280). The test demonstrated that the HF output characteristics of the two generators are substantially equivalent and that there are no differences which would be expected to result in a change in the vessel sealing performance.

An evaluation of the capacitive coupling behavior of the E-200 generator was performed using third party laparoscopic monopolar accessories which included instruments and cannulas. This validation demonstrated that the E-200 generator had no significant increase in unintended capacitively coupled energy delivery when compared to the predicate Covidien ForceTriad generator.

Human Factors Evaluation:

The Usability Validation Study evaluated the use safety and usability of the E-200 generator along with its associated accessories with intended robotic systems in integrated and standalone

configurations. The usability validation study demonstrated that the E-200 electrosurgical generator could be used safely and effectively by the intended users in the intended use environment.

Summary:

The evaluation of the 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 devices, Covidien ForceTRIAD Electrosurgical Generator (K110268) and Intuitive E-100 Electrosurgical Generator (K191280).
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