



August 5, 2024

Intuitive Surgical
Medha Sateesh Bharadwaj
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K241635

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: June 6, 2024
Received: June 6, 2024

Dear Medha Sateesh Bharadwaj:

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.

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

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

Digitally signed by Mark
Trumbore -S
Date: 2024.08.05 09:04:13
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Enclosure

Indications for Use

Submission 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.

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510(k) Summary

Prepared on: 2024-06-06

Contact Details

[21 CFR 807.92\(a\)\(1\)](#)

Applicant Name	Intuitive Surgical
Applicant Address	1266 Kifer Road Sunnyvale CA 94086 United States
Applicant Contact Telephone	631-532-7229
Applicant Contact	Ms. Medha Sateesh Bharadwaj
Applicant Contact Email	medha.sateeshbharadwaj@intusurg.com

Device Name

[21 CFR 807.92\(a\)\(2\)](#)

Device Trade Name	da Vinci E-200 Electrosurgical Generator
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Product Code(s)	GEI

Legally Marketed Predicate Devices

[21 CFR 807.92\(a\)\(3\)](#)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K231212	da Vinci E-200 Electrosurgical Generator	GEI

Device Description Summary

[21 CFR 807.92\(a\)\(4\)](#)

The da Vinci E-200 Electrosurgical Generator 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 Electrosurgical Generator is intended to be used with the da Vinci X, da Vinci Xi, and da Vinci 5 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

[21 CFR 807.92\(a\)\(5\)](#)

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.

Indications for Use Comparison

[21 CFR 807.92\(a\)\(5\)](#)

Indications for use are the same as the predicate device.

Technological Comparison

[21 CFR 807.92\(a\)\(6\)](#)

The technological characteristics of the subject da Vinci E-200 Electrosurgical Generator are the same as the predicate device cleared under K231212. The subject device has the same indication for use, same fundamental scientific technology, and similar technological characteristics as the predicate device. Results from performance data indicate that the subject da Vinci E-200 Electrosurgical Generator is substantially equivalent to the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions [21 CFR 807.92\(b\)](#)

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

Design Verification (Bench Testing)

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

- Software requirements, including cybersecurity
- EMC and Electrical Safety requirements
- System interface requirements
- Instrument compatibility requirements
- Packaging and Labeling

Design Validation

Simulated clinical use testing was performed with a porcine model to validate that the product specifications continued to meet the users' needs and intended use.

Human Factor Evaluation testing:

The Human factor evaluation determined that the subject da Vinci E-200 Electrosurgical Generators are safe and effective for their intended uses by the intended users, in the intended use environment.

Based on the indications for use, technological characteristics, and performance data, the subject da Vinci E-200 Electrosurgical Generator is substantially equivalent to the predicate device (K231212).