Intuitive Surgical
Prerna Singh
Senior Regulatory Affairs Specialist
1266 Kifer Road
Sunnyvale, California 94086

Re: K241621
Trade/Device Name: Da Vinci Monopolar and Bipolar Adapters (378896)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 5, 2024
Received: June 5, 2024

Dear Prerna Singh:

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,

Francisco Delgado -S
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for Mark Trumbore
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

Device Name

Da Vinci Monopolar and Bipolar Adapters (378896)

Indications for Use *(Describe)*

The Da Vinci Monopolar and Bipolar Adapters are intended for connecting monopolar or bipolar electrosurgical instruments to an electrosurgical generator to provide transmission of high frequency energy from the electrosurgical generator to the surgical instrument.

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.

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510(k) Summary

510(k) Owner:
Intuitive Surgical, Inc.
1266 Kifer Road
Sunnyvale, CA 94086

Contact Person:
Prerna Singh
Sr. Regulatory Affairs Specialist
Phone: 310-592-6866
Email: prerna.singh@intusurg.com

Date Summary Prepared: June 5, 2024

I. SUBJECT DEVICE

Trade Name: Da Vinci Monopolar and Bipolar Adapters
Common Name: Generator Adapters
Classification: Class II, Electrosurgical, Cutting & Coagulation & Accessories (21 CFR 878.4400)
Product Code: GEI

II. PREDICATE DEVICE

Olsen Medical Electrosurgical Cables/Adapters, K111262

III. DEVICE DESCRIPTION

The Da Vinci Monopolar and Bipolar Adapters are an accessory for the Da Vinci E-200 Electrosurgical Generator (**K223039, K231212**). The Da Vinci Monopolar and Bipolar Adapters (referred to herein as "Adapters") are non-sterile. They are designed to enable the use of certain, third-party electrosurgical instruments with specific monopolar and bipolar plug formats (refer to with the E-200 Electrosurgical Generator). This enables the transmission of high-frequency energy from the electrosurgical generator to the surgical instrument.

IV. INTENDED USE/INDICATION FOR USE

The Da Vinci Monopolar and Bipolar Adapters are intended for connecting monopolar or bipolar electrosurgical instruments to an electrosurgical generator to provide transmission of high frequency energy from the electrosurgical generator to the surgical instrument.

V. TECHNOLOGICAL CHARACTERISTICS

The subject device Adapters are same to its predicate device cleared under **K111262**. 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 Adapters are substantially equivalent to the Predicate device Olsen Medical Electrosurgical Cables/Adapters.

VI. PERFORMANCE DATA

Verification and validation activities were successfully completed that establish that the subject device performs as intended and is substantially equivalent to its predicate, Olsen Medical Electrosurgical Cables/Adapters. 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:

- Hardware requirements
- Reliability requirements
- EMC and Electrical Safety requirements
- Packaging and Labeling

Design Validation
Simulated clinical use testing was performed with a cadaver model to validate that the product specifications continued to meet the user's needs and intended use.

Human Factor Evaluation testing:
The Human factor evaluation determined that the Adapters are safe and effective for their intended uses by the intended users, in the intended use environment.

Transit Testing
Transit testing was performed in accordance with *ASTM D4169-22, Standard Practice for Performance Testing of Shipping Containers and Systems*

VII. CONCLUSIONS

Based on the indications for use, technological characteristics, and performance data, the subject Adapters are substantially equivalent to the predicate device.