November 14, 2019

Intuitive Surgical, Inc.
Melissa Gonzalez
Regulatory Project Manager
1266 Kifer Road
Sunnyvale, California 94086

Re: K191280
Trade/Device Name: E-100 Electrosurgical Generator, SynchroSeal
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: NAY, GEI
Dated: October 15, 2019
Received: October 16, 2019

Dear Melissa Gonzalez:

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,

Jitendra Virani
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191280

Device Name
E-100 Electrosurgical Generator and SynchroSeal Instrument

Indications for Use *(Describe)*
SynchroSeal is a bipolar electrosurgical instrument for use with a compatible da Vinci Surgical System and a compatible electrosurgical generator. It is intended for grasping, dissection, sealing and transection of tissue. SynchroSeal can be used to seal vessels up to and including 5 mm in diameter and tissue bundles that fit in the jaws of the instrument. SynchroSeal 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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:

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191280

Device Name
E-100 Electrosurgical Generator and SynchroSeal Instrument

Indications for Use *(Describe)*
The E-100 is an electrosurgical generator for use with a compatible da Vinci Surgical System. It is an electrosurgical unit intended to deliver high frequency energy (HF) for cutting, coagulation and vessel sealing of tissues.

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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6 510(k) Summary – K191280

510(k) Summary – K191280

[As Required by 21 CFR 807.92(c)]

May 10, 2019

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

Official Contact: Melissa Gonzalez
Regulatory Project Manager
Ph: 408-523-8684
Fax: 408-523-8907

Trade Name:

Generator: E-100 Electrosurgical Generator
Instrument: SynchroSeal

Common Name:

Generator: Electrosurgical Unit (ESU/Generator)
Instrument: System, surgical, computer controlled instruments

Classification:

Generator: Class II, 21 CFR 878.4400, Electrosurgical, Cutting & Coagulation & Accessories
Instrument: Class II, 21 CFR 876.1500, Endoscope and Accessories

Product Codes: **Primary:** NAY (Endoscope and Accessories)
Secondary: GEI (Electrosurgical, Cutting & Coagulation & Accessories)

Predicate Device:

Generator: ERBE VIO dV (K150364)
Instrument: *EndoWrist*® Vessel Sealer Extend (K183107)

Reference Device:

Generator: JustRight Surgical Vessel Sealing System (K160602)

Device Description:

Generator: The E-100 Electrosurgical Generator is an electrosurgical generator intended to deliver High Frequency (HF) energy for cutting/transection, coagulation and vessel sealing of tissues when used with compatible "Intuitive Surgical Advanced Energy" bipolar instruments –"SynchroSeal" and "Vessel Sealer Extend". The generator provides a single HF output port into which one of these compatible surgical instruments may be plugged.

The primary function of the E-100 Electrosurgical Generator is to allow a surgeon to deliver HF output to cut, seal, or coagulate human tissue during surgery. The generator regulates the HF output to achieve the intended surgical effect by using instrument specific algorithms, which adjust HF output in reaction to time and tissue impedance. The user interface provides audible indicator tones, lighted indications on the front of the generator, as well as messages displayed on the da Vinci system monitors.

The intended targeted surgical applications are for robotic procedures that may utilize vessel sealing applications or rapid hemostatic transection of tissue.

Instrument: SynchroSeal is a single-use, disposable, 8 mm instrument with an integrated cord that connects to the E-100 Electrosurgical Generator. An electrode sealing surface and a protruding cut electrode within the jaws enable sealing and cutting/transection functionality. SynchroSeal is an advanced, wristed, bipolar instrument that provides a unique energy mode to enable sealing and transection of vessels and tissue bundles with a single pedal press. In addition to this functionality, SynchroSeal has the ability to grasp, dissect and spot coagulate tissue, and to independently seal vessels.

The SynchroSeal instrument is designed to be used in conjunction with the IS4000 and IS4200 Surgical Systems. Use of the SynchroSeal instrument is limited to surgical applications of the E-100 Generator.

Intended Use/Indications for Use:

Generator: The E-100 is an electrosurgical generator for use with a compatible *da Vinci* Surgical System. It is an electrosurgical unit intended to deliver high-frequency energy (HF) for cutting, coagulation and vessel sealing of tissues.

The difference in the Intended Use statements between the subject device and the predicate device is in the lack of sealing indication in the predicate device.

As demonstrated by the bench and animal performance data, addition of vessel sealing did not alter the intended use compared to the intended use of the predicate device, ERBE VIO dV (K150364). In order to demonstrate safety and efficacy of the subject device, the sealing performance of the VSE with the Erbe VIO dV was used as the benchmark for bench and in-vivo vessel sealing validation testing because the Erbe VIO dV is the only generator that is compatible with both the da Vinci robot and the VSE instrument. Additionally, the Erbe VIO dV generator is currently used in conjunction with the currently marketed da Vinci VSE instrument for vessel sealing.

Instrument: SynchroSeal is a bipolar electrosurgical instrument for use with a compatible da Vinci Surgical System and a compatible electrosurgical generator. It is intended for grasping, dissection, sealing and transection of tissue. SynchroSeal can be used to seal vessels up to and including 5 mm in diameter and tissue bundles that fit in the jaws of the instrument. SynchroSeal has not been shown to be effective for tubal sterilization or tubal coagulation for sterilization procedures and should not be used for these procedures.

There are two (2) distinct changes to the Indications for Use and Intended Use compared to the predicate device:

Dissection (Blunt not specified): Both devices are intended for dissection. The instrument tip of the subject device is designed to allow more precise dissection, in addition to the blunt dissection intended by the predicate device. The difference in the instrument tip was evaluated and did not negatively impact the safety or effectiveness of the subject device.

Target Vessel Size (5 mm for the subject device vs. 7mm for the predicate device): The change in target vessel (and tissue bundle size) is the result of the smaller jaw profile and integrated HF cutting blade in the subject device. The difference in target vessel size was evaluated and did not negatively impact the safety or effectiveness of the subject device.

Technological Characteristics:

Generator: The E-100 Electrosurgical Generator is a high-frequency energy (HF) generator designed to be used with compatible Intuitive Surgical Advanced Energy instruments (Vessel Sealer Extend and SynchroSeal). The E-100 Electrosurgical Generator has 3 HF output modes:

Sealing Mode – The E-100 Sealing mode provides a bipolar output which is designed to seal vessels and tissue bundles when used with the Vessel Sealer Extend and SynchroSeal instruments.

Sync Mode – The E-100 Sync mode provides a combined bipolar cut and seal output to enable single step hemostatic transection of vessels and tissue bundles when used with the SynchroSeal instrument.

Coag Mode – The E-100 Coagulation mode provides a traditional bipolar output for coagulating tissues when used with the Vessel Sealer Extend and SynchroSeal instruments.

The E-100 Electrosurgical Generator is intended to be used with both the da Vinci Xi and X Surgical Systems, and fits in the da Vinci Xi and X vision carts as an optional add-on accessory. The E-100 Electrosurgical Generator communicates with the da Vinci Xi or X systems over a proprietary serial interface.

The E-100 Electrosurgical Generator uses a plug-and-play user interface where the generator automatically delivers the HF output mode which corresponds to the predetermined settings for the instrument inserted by the user. Sealing Mode, Sync Mode and Coag mode are communicated to the generator based on user input from the surgeon console. Instrument activation and status information is communicated to the user via the user interface on both the generator and the surgeon console.

There are several minor differences in technological characteristics, as compared to the predicate and/or reference device:

Major functions of ESU (Generator): Because the E-100 Electrosurgical generator is intended for use only with two Advanced Bipolar Intuitive Surgical instruments, Vessel Sealer Extend (VSE) and SynchroSeal instruments, its features represent a subset of those that are included in the predicate. Erbe VIO dV provides monopolar and bipolar outputs to support standard monopolar, bipolar, and Advanced Bipolar Intuitive Surgical instruments as well as third party instruments, while E-100 only provides bipolar outputs to support VSE and SynchroSeal.

User Interaction: The subject device does not have user adjustable output settings and therefore does not have its own LCD display. Usability validation was conducted with the subject device and the differences in user interaction do not impact safety and effectiveness of the subject device as compared to the predicate device.

Sealing Endpoint Detection: The subject device includes Sealing Endpoint Detection, which is a method of using impedance to detect completion of a seal sequence. The predicate device monitors the change of tissue impedance over time, and uses this information to automatically stop energy delivery. The subject and reference devices monitor predetermined impedance and use this information to automatically stop energy delivery. As demonstrated by the device performance testing, the difference between the endpoint detection methods does not impact the safety and effectiveness of the subject device.

Performance Specification: The JustRight Surgical Vessel Sealing System (K160602) was included in this submission as a reference device because, like the E-100 generator, it incorporates a similar low power vessel sealing technology that differs from traditional vessel sealing systems which utilize a modulated, higher power output.

The differences between the electrical characteristics of the output between the subject and predicate device, ERBE VIO dV (K150364) do not affect safety and effectiveness as demonstrated in Performance Testing.

Instrument: SynchroSeal, when used with a compatible electrosurgical generator, creates a seal and transects tissue by application of HF energy to vessels and tissue bundles that fit in the jaws of the instrument. Electrode sealing surfaces and a cut electrode within the jaws enable sealing and cutting, respectively. In addition, SynchroSeal has the ability to grasp, dissect and spot coagulate tissue, and to independently seal vessels.

There are several minor differences in technological characteristics, as compared to the predicate device:

General Design: (Electrosurgical vs. mechanical transection/cutting): As indicated in the Indications for Use, Intended Use and Tip (Distal End), the subject device uses bipolar energy to enable hemostatic cutting of vessels and/or tissue bundles in a single pedal press (SYNC), as opposed to two distinct actions required to achieve the same clinical effect (SEAL and CUT) using the predicate device. The difference in energy output (electrosurgical vs. mechanical) was evaluated and did not negatively impact the safety or effectiveness of the subject device.

Patient Contact Materials: The additional materials used in the subject device have been evaluated according to the requirements of ISO 10993-1. These results demonstrate that the SynchroSeal instrument is non-hemolytic, does not cause intracutaneous irritation, skin sensitization, acute systemic toxicity, and is non-pyrogenic. Furthermore, this testing identified no issues of safety or effectiveness and no new risks.

Design Attributes: Tip (Distal End): Several changes were made to the distal end of the subject instrument to simplify the design and reduce the overall jaw profile. These changes were evaluated with a combination of bench-top and animal testing (acute and chronic) and were determined to not negatively impact the safety and effectiveness of the subject device.

Physical Dimensions (including Jaw Length, Jaw Width, Transection/Cut Distance, Position of Cut Length Indicator, Electrode Surface Area, and Electrode Spacing): The changes in these physical dimensions are a result of the design optimized for a smaller jaw profile. These changes were evaluated with a combination of bench-top and animal testing (acute and chronic) and were determined to not negatively impact the safety and effectiveness of the subject device.

Description of User Interface:

Generator: The E-100 Electrosurgical Generator alerts the user to conditions that could impact procedural results. The E-100 Electrosurgical Generator status is communicated by illuminating the bipolar port LED and Power button in conjunction with producing audible tones. The bipolar port LED and Power button employ the use of color and flashing to communicate status. In some conditions, a message regarding E-100 Electrosurgical Generator status is displayed on the da Vinci System's monitors.

Instrument: The User Interface for the instrument is contained within/on the generator and/or da Vinci Systems.

Performance Data:

Generator: The E-100 Electrosurgical Generator was evaluated using bench testing, human factors testing, packaging and transit testing, validation in clinical models (animals/cadavers) and a chronic animal study (in-vivo) to demonstrate that the design output meets the design input requirements and the generator performs as intended.

Design Verification (bench testing): The subject device, E-100 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 included confirmation that the device meets the requirements in the protocols listed below:

- Hardware Requirements, including:
  - physical measurements,
  - general functionality,
  - function of electrical components, and
  - reliability.
- EMC and Safety requirements
- Software requirements, including
  - power on/self-test,
  - communications monitoring,
  - instrument detection and compatibility (VSE and SynchroSeal),
  - energy delivery and control,
  - user interface,
  - hardware health monitoring, and
  - system communication (i.e. system interface requirements).

Design Validation (animal/cadaver): The safety and efficacy of the E-100 Electrosurgical Generator and the instruments were assessed in representative simulated clinical settings that utilized porcine models (*in vivo and ex vivo*) and cadavers to evaluate applicable requirements through expected clinical use. Representative tissue types were used, as appropriate, for evaluating applicable requirements. Design validation demonstrated that the design outputs fulfill the user needs and that the intended use, including indicated vessel sizes, have been met.

Chronic Animal Study (animal): A chronic animal study was performed to evaluate the clinical performance (long-term seal quality) of the subject device, E-100 Electrosurgical generator SynchroSeal, and Vessel Sealer Extend, as compared to the predicate devices, ERBE VIO generator and *EndoWrist* Vessel Sealer Extend. This study allowed for the clinical assessment of vascular seal performance and the vascular healing response in a live animal model with similar human tissue characteristics and a similar abdominal cavity.

Instrument: SynchroSeal was evaluated using human factors testing, biocompatibility testing, sterilization testing, packaging and transit testing, verification testing, validation testing in clinical models (animals/cadavers) and a chronic animal study (in-vivo) to

demonstrate that the design output meets the design input requirements and the device performs as intended.

Design Verification bench: The subject device, SynchroSeal, was subjected to series of bench tests to evaluate performance and to demonstrate that the design outputs meet the design input requirements. Testing was performed with the E-100 Electrosurgical Generator and a compatible da Vinci *s*urgical system. The design verification testing included confirmation that the device meets the:

- Physical Specifications, including:
    - critical dimensions (jaw length/width, electrode spacing),
    - mass,
    - material specifications, and
    - jaw to failure.
- Mechanical Requirements, including:
    - range of motion,
    - grip force,
    - transection/cut distance
    - alignment, and
    - reliability.
- Electrical Requirements, including:
    - leakage,
    - creepage & clearance,
    - electrostatic discharge, and
    - isolation, etc.
- User Interface Requirements
- Equipment Interface Requirements, including:
    - Data verification,
    - Instrument recognition and engagement,
    - Guided tool change,
    - Gravity compensation

Design Validation (animal/cadaver): The safety and efficacy of the E-100 Electrosurgical Generator and the instrument was assessed in representative simulated clinical settings that utilized porcine models (*in vivo and ex vivo*) and/or cadavers to evaluate applicable requirements through expected clinical use. Representative tissue types were used, as appropriate, for evaluating applicable requirements. Design

validation demonstrated that the design outputs fulfill the user needs and that the intended use, including indicated vessel sizes, have been met.

Chronic Animal Study: A chronic animal study was performed to evaluate the clinical performance (long-term seal quality) of the subject device, E-100 Electrosurgical generator and SynchroSeal, as compared to the predicate device, ERBE VIO generator and *EndoWrist* Vessel Sealer Extend. This study allowed for the clinical assessment of vascular seal performance and the vascular healing response in a live animal model with similar human tissue characteristics and a similar abdominal cavity.

Summary:

The E-100 Electrosurgical Generator and SynchroSeal instrument raise no new questions of safety or effectiveness. Based on their intended use, technical characteristics, and performance data, the E-100 Electrosurgical Generator and SynchroSeal instrument are equivalent to their respective predicate devices in terms of safety, effectiveness, and performance.