December 12, 2023

Innoblative Designs, Inc.
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K232947
Trade/Device Name: SIRA™ RFA Electrosurgical Device
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 20, 2023
Received: September 20, 2023

Dear Janice Hogan:

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

Digitally signed by Mark Trumbore -S
Date: 2023.12.12 16:52:53 -05'00'

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: 07/31/2026
See PRA Statement below

510(k) Number *(if known)*

K232947

Device Name

SIRA RFA Electrosurgical Device

Indications for Use *(Describe)*

The SIRA™ RFA Electrosurgical Device supplies energy for use in electrosurgery and is indicated for use in intraoperative coagulation and ablation of soft tissue. The SIRA™ RFA Electrosurgical Device is to be used in conjunction with a radiofrequency (RF) electrosurgical generator for use in open abdominal surgical procedures. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

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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K232947

510(k) SUMMARY

Innoblative Designs' SIRA™ RFA Electrosurgical Device

Name of Device and Name/Address of Sponsor

SIRA™ RFA Electrosurgical Device
Innoblative Designs, Inc.
1623 W. Fulton St.
Chicago, IL 60612

Phone: 860-833-5002

Contact Person: Katherine Crowley

Date Prepared: November 14, 2023

Common or Usual Name

Electrosurgical Device

Classification Name

21 CFR 878.4400, Class II, product code GEI

Predicate Devices

Innoblative Designs SIRA™ RFA Electrosurgical Device, K181071

Purpose of the Special 510(k) notice.

The SIRA™ RFA Electrosurgical Device, model number SIRA-1000, is a modification to the predicate device (K181071). The primary modifications are different biocompatible materials, a modified design to improve manufacturability, and updated electrical components with an updated PCB layout.

Intended Use

The SIRA™ RFA Electrosurgical Device supplies energy for use in electrosurgery and is indicated for use in intraoperative coagulation and ablation of soft tissue. The SIRA™ RFA Electrosurgical Device is to be used in conjunction with a radiofrequency (RF) electrosurgical generator for use in open abdominal surgical procedures. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

Device Description

The SIRA™ RFA Electrosurgical Device, model number SIRA-1000, is a sterile, single-use electrosurgical device, which is for use in the intraoperative coagulation and ablation of soft tissue. The SIRA-1000 is supplied STERILE using an ethylene oxide (EO) process.

The device is a single-use device that can be used for multiple applications in one operative site. The SIRA-1000 is to be used in conjunction with a bipolar electrosurgical generator (e.g., Medtronic ForceTriad Generator).

The SIRA-1000 is a prescription Class II device.

The SIRA-1000, shown in **Figure 1** below, consists of an electrode array with an internal irrigation chamber, a cable assembly, and an integrated switch and timer.

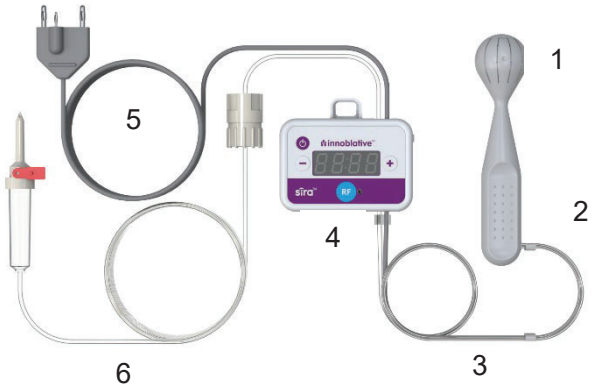

Figure 1: SIRA™ RFA Electrosurgical Device components

1. 4cm diameter electrode array (“applied part”),
2. Handle (shaft),
3. Probe cable and saline tube,
4. Integrated switch and timer,
5. Main cable with a connector to interface with standard RF electrosurgical generators for transmitting the radiofrequency energy, and
6. Fluid administration set with a flow regulator for saline infusion.

Technological Characteristics

The SIRA-1000 has the same technological characteristics as the originally cleared predicate device, to which it is a modification.

The designs of both the SIRA-1000 and its predicate device consist of an electrode array at the end of an ergonomically designed body. Both the SIRA-1000 and the predicate deliver bipolar radiofrequency energy coupled with 0.9% saline to coagulate and ablate soft tissue. Both devices are sterile, single-patient use, and disposable. Further, both the subject and predicate device consist of

an integrated cable assembly that connects the devices to an electrosurgical generator. Both the subject and predicate devices are electrically insulated, except for the electrode array that is electrically active. Both the subject device and predicate allow the user to control the availability and duration of RF energy present at the electrode array. In addition, both the subject and predicate devices are required to be used with the same accessories, including a 0.9% saline bag, an IV pole, and an external electrosurgical generator.

Saline infusion is provided by both subject and predicate and is controlled by a manual flow regulator with settings of 0-300 ml/hr. The overall size of the working end of the SIRA-1000 is the same as the predicate device.

Therefore, the SIRA-1000 has the same technological characteristics as its predicate device and is substantially equivalent.

Performance Data

The following nonclinical performance testing has been conducted to support the substantial equivalence of the SIRA-1000 to its predicate. In all instances, the subject device functioned as intended.

- Software verification and validation was performed and demonstrated that the software performs as intended.
- Electrical safety (IEC 60601-1) and electromagnetic compatibility (IEC 60601-1-2) testing was conducted, and results were passing.
- Biocompatibility of the patient-contacting components of the device was established.
- Performance bench testing was conducted, including mechanical testing, dimensional testing, and functional tests, demonstrating the device functions as intended.
- Packaging testing was conducted with passing results.

Substantial Equivalence

The SIRA-1000 has the same indications for use, principles of operation, and technological characteristics as the predicate device. The minor technological differences between the subject and the predicate device do not raise different questions of safety or effectiveness. Performance testing of the device has demonstrated that the device performs as intended and thus, is substantially equivalent.

Conclusion

The SIRA-1000 has been evaluated in performance testing. The test results discussed above demonstrate that the device is as safe, as effective, and performs as well as the predicate device.