January 16, 2019

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

Re: K181071
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: December 18, 2018
Received: December 18, 2018

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 (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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2019.01.16 16:05:02 -05'00'

for

Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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 on last page

510(k) Number *(if known)*

K181071

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 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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510(k) SUMMARY

Innoblative Designs, Inc.'s SIRA™ Device

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Tyler Wanke, President and CEO
Innoblative Designs, Inc.
4660 Ravenswood Avenue
Chicago, IL 60640
Phone: 920-450-7529

Date Prepared: January 14, 2019

Name of Device

SIRA™ RFA Electrosurgical Device

Common or Usual Name

Electrosurgical Device

Classification

21 CFR 878.4400, Class II, product code GEI

Predicate Device

Medtronic Aquamantys Malleable Bipolar Sealer with Light (K073495)

Intended Use / Indications for 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 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 is used for the simultaneous administration of RF energy and saline for the coagulation and ablation of soft tissue in open intraoperative procedures. The SIRA™ RFA Electrosurgical Device is comprised of a 4cm diameter electrode array, a handle (shaft), a co-extruded cable, an integrated electrical RF switch and timer, a main cable, and a fluid administration set.

Technological Characteristics

The SIRA™ RFA Electrosurgical Device has similar technological characteristics as its predicate device.

The designs of both the SIRA™ RFA Electrosurgical Device and Aquamantys predicate consist of an electrode tip/shaft assembly extended out of an ergonomically designed body. Both the SIRA™ RFA and the Aquamantys devices deliver bipolar radiofrequency energy coupled with 0.9% saline to coagulate 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. Furthermore, both the subject and predicate devices are electrically insulated, except for the tip of the shaft that is electrically active. Both the subject device and Aquamantys predicate allow the user to control the level of RF energy and duration. In addition, both the subject and predicate devices are required to be used with similar accessories, including a 0.9% saline bag, an IV pole, and an external electrosurgical generator.

Although the saline flow for the subject device is controlled by a manual flow regulator with settings of 5-300 ml/hr, whereas the saline flow for the predicate Aquamantys is controlled by an automatic saline pump with low, medium, and high settings, this minor difference does not raise new questions of safety or effectiveness because both devices provide an appropriate mechanism for saline infusion. In addition, the overall size of the working end of the SIRA™ RFA device is larger than the predicate device's electrodes, which can result in larger contact surface area than the predicate with each ablation lesion delivery. However, the differences in dimensions do not raise new questions of safety or effectiveness. Furthermore, comparative testing demonstrates that the depth of treatment created by both devices is equivalent when energy is applied at similar durations, with similarly applied energy levels.

Therefore, the SIRA™ RFA Electrosurgical Device has very similar 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™ RFA Electrosurgical Device 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 IEC 60601-2-2) 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.
- Sterility validation was established for all required components.
- Performance bench testing, including predicate comparative testing, mechanical testing, dimensional testing, functional tests.
- In vivo testing in an animal model was performed to evaluate and establish the safety and effectiveness of the subject device.
- Usability testing to demonstrate that the intended users of the device can use the device as intended to coagulate/ablate soft tissues without patterns of perceptible use errors or difficultly that could result in serious harm to the user or patient.

Substantial Equivalence

The SIRA™ RFA Electrosurgical Device has the same indications for use and similar indications for use, as well as very similar technological characteristics, and principles of operation as its 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™ RFA Electrosurgical Device has been evaluated in performance testing. Testing demonstrates that the device performs as intended. The SIRA™ RFA Electrosurgical Device is substantially equivalent to its predicate device.