March 11, 2019

Agency for Medical Innovations GmbH
% Dr. Pierre Bounaud
Acknowledge Regulatory Strategies, LLC
2251 San Diego Ave., Suite B-257
San Diego, California 92110

Re: K182013
Trade/Device Name: EasyInstruments
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories.
Regulatory Class: Class II
Product Code: GEI
Dated: January 25, 2019
Received: January 29, 2019

Dear Dr. Bounaud:

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 and Part 809); 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: 2019.03.11 14:07:57 -04'00' 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K182013

Device Name
EasyInstruments

Indications for Use *(Describe)*
The Easylnstruments are indicated for cutting, grasping, dissecting and coagulation of tissue in laparoscopic surgical 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

510(k) Summary

DATE PREPARED
February 26, 2019

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PROPRIETARY NAME OF SUBJECT DEVICE
EasyInstruments

COMMON NAME
Electrosurgical, Cutting & Coagulation & Accessories

DEVICE CLASSIFICATION
Electrosurgical cutting and coagulation device and accessories
(21 CFR 878.4400, Product Code GEI, Class II)

PREMARKET REVIEW
ODE/DSD/GSDB2
General & Plastic Surgery Panel

PREDICATE DEVICE IDENTIFICATION

EasyInstruments device is substantially equivalent to the following predicates:

510(k) Number	*Predicate Device Name / Manufacturer*	*Primary Predicate*	*Reference Predicate*
K962119	ReNew Laparoscopic Instruments / Microline	✓	
K160706	ReNew V Handpiece Laparoscopic Instruments / Microline		
K163615	Snowden-Pencer Microlap 3mm Laparoscopic Instruments / CareFusion 2200 Inc.		
K933002	Erbotom ICC 350 / Erbe USA, Inc.		✓
K023886	Erbe VIO ESU with Accessories, Model VIO 300 D / Erbe USA, Inc.		✓

DEVICE DESCRIPTION

The A.M.I. EasyInstruments device is a modular instrument system for use in laparoscopic high-frequency (HF) surgery and is designed for monopolar application. The EasyInstruments system comprises three-part detachable instruments, which include 1) different functional handles (EasyHandle), 2) instrument shafts of various diameters and lengths (EasyShaft), and 3) a wide range of different, application-specific attachments (EasyTips). It is intended during laparoscopic procedures to mobilize, manipulate, grasp, hold, fix, retract, dissect, cut, and coagulate tissue.

INDICATIONS FOR USE

The EasyInstruments are indicated for cutting, grasping, dissecting and coagulation of tissue in laparoscopic surgical procedures.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The subject device has a similar design and dimensions and uses similar materials as the devices cleared in K962119, K160706, and K163615. The subject device has equivalent general intended use and similar technological characteristics as the device cleared in K962119, K160706 and K163615. Unlike the predicate devices, the tips, shafts and handles of EasyInstruments are detachable, which allows for easier cleaning and reprocessing of the instruments. A smaller shaft (3 mm) and the associated smaller length of the shaft/handle combination (17 and 26.5 cm) provide the surgeon with more options during laparoscopic procedures. An ergonomic fingertrip trigger is available on the EasyAct device to facilitate coagulation of tissue.

SUMMARY OF NON-CLINICAL TESTING

Testing was performed per FDA's guidance document *Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery (Issued August 15, 2016)*.
A summary of the following tests that were performed was provided in order to demonstrate safety based on current industry standards:

- Cleaning validation per AAMI TIR12 and AAMI TIR30
- Sterilization validation per ISO 17665-1, ISO 11135, and ISO 11137
- Shelf life and packaging validation per ISO 11607
- Biocompatibility Risk Assessment per ISO 10993-1
- Cytotoxicity testing per ISO 10993-5
- Irritation and sensitization testing per ISO 10993-10
- Electrical safety per IEC 60601-1 and IEC 60601-2-2
- EMC per IEC 60601-1-2
- Bench performance testing, including performance of disposable tips, performance of reusable tips after reprocessing, performance of EasyHandle reprocessing, and performance of EasyShaft after reprocessing. Performance tests for the tips included visual inspection for damage, opening angle, ease of movement in opening/closing, cutting, dissecting, grasping strength, continuity check between shaft and tip, and compatibility check of the shaft with tips. Performance tests for EasyShaft and EasyHandle included visual inspection (i.e. cracks, damage, warpage), continuity check between shaft and tip, dielectric strength of the shaft, and compatibility check of the shaft with tips.
- Thermal effects on tissue. Side by side testing was performed on *ex vivo* animal tissues (liver, kidney, and muscle) and thermal damage was assessed by measuring the depth of damage at minimum, default, and maximum power settings using histology.
- Usability testing per IEC 62366-1, including device assembly, device disassembly, device reprocessing, and device application in a simulated environment

The results of these tests indicate that the EasyInstruments are substantially equivalent to the predicate devices.

CONCLUSION

Based on the testing performed, including biocompatibility, cleaning validation, sterilization validation, shelf life validation, packaging validation, electrical safety, EMC testing, non-clinical performance testing (bench), thermal effects on tissue, and usability testing, it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate devices. The equivalent indications for use, technological characteristics, and performance characteristics for the proposed EasyInstruments are assessed to be substantially equivalent to the predicate devices.