



Food and Drug Administration
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March 7, 2016

Elliquence LLC.
Mr. Paul Buhrke IV
QA/RA Manager
2455 Grand Avenue
Baldwin, New York 11510

Re: K160041

Trade/Device Name: Cobbra RF Tissue Dissector
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: January 6, 2016
Received: January 8, 2016

Dear Mr. Buhrke:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Jennifer R. Stevenson -A

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

Indications for Use

510(k) Number (if known)
K160041

Device Name
Cobra RF Tissue Dissector

Indications for Use (Describe)

The Cobra RF Tissue Dissector is intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures. The types of surgery intended are: General surgery, Laparoscopic procedures, Endoscopic procedures, Open abdominal, Orthopedic coagulation, Thorascopic coagulation, Neurosurgical coagulation Gynecological coagulation, (except for use in female sterilization), Ear, Nose, Throat coagulation.

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
(As required by 21 CFR 807.92(a))

Date Prepared

January 6, 2016

Submitter's Information (807.92(a)(1))

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Device Information (807.92(a)(2))

Trade Name
Cobra™ RF Tissue Dissector

Common/Usual Name
Monopolar electrosurgical device



Classification Name and Regulation

Electrosurgical Cutting and Coagulation Device and Accessories; 21 CFR 878.4400.

Class

FDA Classification: Class II

FDA Product Code: GEI

Predicate Devices (807.92(a)(3))

- Elliquence Electrodes (510(k) K142410)
- PEAK Surgery System (510(k) K082786)

Device Description (807.92(a)(4))

The Cobbra™ RF Tissue Dissector is a single-use, sterile, monopolar electrosurgical instrument intended for use exclusively with the elliquence Surgi-Max® / Surgi-Max® Plus radiofrequency generator (510(k) K100390). The basic design of the device is a plastic handpiece, a partially-insulated electrode with an uninsulated, active edge, and a cable and plug. The electrical power operating at radio frequency (RF) is transferred to tissue at the surgical site via the active edge of the Cobbra™ RF Tissue Dissector's electrode. The time-varying voltage produced by RF electrical power source yields a predetermined electrosurgical effect, such as tissue cutting or coagulation.

The Cobbra™ RF Tissue Dissector is classified as a sterile, surgically-invasive, active device with an intended patient contact period of <1hr (transient). It is composed of 17-4PH medical-grade stainless steel, ABS plastic, PFA, PVC, and copper. The biocompatibility of patient contacting materials has been assured through appropriate testing in accordance with ISO 10993-1.

The Cobbra™ RF Tissue Dissector is individually-packaged and supplied EtO-sterilized for single use. It is available in five models which differ only by the diameter of the electrode: RF-COBB/XS (0.25 in.), RF-COBB/S (0.375 in.), RF-COBB/M (0.5 in.), RF-COBB/L (1.0 in.), and RF-COBB/XL (1.5 in.).

Intended Use (807.92(a)(5))

The Cobbra™ RF Tissue Dissector is intended for use by a physician familiar with resection, dissection, incision, and hemostasis in soft tissue surgical procedures. The types of surgery intended are: General surgery, Laparoscopic procedures, Endoscopic procedures, Open

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abdominal, Orthopedic coagulation, Thorascopic coagulation, Neurosurgical coagulation, Gynecological coagulation, (except for use in female sterilization), and Ear, Nose, Throat coagulation.

Substantial Equivalence Comparison (807.92(a)(6))

The Cobbra™ RF Tissue Dissector is substantially equivalent in its intended use, technology/principle of operation, materials, and performance to the two chosen predicate devices:

- (1) elligence Electrodes (510(k) K142410)
- (2) PEAK Surgery System (510(k) K082786)

An extensive comparison chart and discussion is provided within the 510(k) submission.

Non-Clinical Testing (807.92(b)(1))

Bench testing performed to support substantial equivalence included:

- Various performance tests including mechanical testing, thermal damage measurements, and simulated use tests
- Applicable biocompatibility tests conducted in accordance with ISO 10993-1
- Electrical safety and electromagnetic compatibility testing in accordance with IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-2
- Testing to support the shelf life determination and sterility of the product

Clinical Testing (807.92(b)(2))

This premarket submission did not rely on the assessment of clinical performance data to demonstrate substantial equivalence.

Conclusion (807.92(b)(3))

Based upon a comparison of the intended uses, technological characteristics, and performance testing, we have concluded that the subject device is as safe and effective as the predicate devices.