K100390

510 (k) Summary

Date Prepared

AUG 25 2010

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Submitter's Information

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Manufacturer/Sponsor:
Elliquence LLC
3333 Royal Avenue
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Establishment Registration for Elliquence LLC Inc. is 3007024186.

Device Trade Or Proprietary Names

Possible device trade names are:

- SurgiMax
- SurgiMax Plus

Device Common, Usual, or Classification Names

Electrosurgical Unit and Accessories, Electrosurgical Cutting and Coagulation and Accessories

Classification Panel

Classification of this device would fall under the responsibility of the Division of General, Restorative, and Neurological Devices.

Class

Classification: Class 2

Product Code: GEI, 21 CFR 878.4400

Description of the Device

The SurgiMax / SurgiMax Plus is a compact source of high radiofrequency energy employed for a variety of procedures. This action is achieved by front panel selection of waveforms and power levels. The subject device can be used with monopolar or bipolar devices. The energy is used for cutting, coagulation, and hemostasis.

The SurgiMax / SurgiMax Plus Electrosurgery Generator is a compact source of high radio-frequency RF energy to be employed for a variety of radiosurgery procedures. This action is achieved by front panel selection of waveforms and power level. All selection is effected through push buttons and lamps, which give the operator feedback of status.

Power level for each mode is indicated by front panel digital displays, which also show the status of self-test and monitoring. The display is interlocked with controls to prevent operation when FAIL is displayed. The final output power control is made through foot and/or hand switches. Both Monopolar and Bipolar electrodes are offered.

This device is designed to comply with international safety standards including applicable IEC series electrical safety standards.

The power output in the CW (Cut) mode is 120 watts into (500 ohms) a matched load. The output frequency is maintained at 4.0 MHz +/- 400Hz over all service and loading conditions including short and open for monopolar mode.

Three output waveforms are provided:

CW CUT – Continuous wave output with average power equal to the maximum with no deliberate modulation.

CUT / COAG – Deeply modulated envelope with average to peak power ratio approximately 50%. Modulation occurring at 75 Hz rate.

HEMO – Deeply modulated wave with average to peak ratio approximately 50%. Modulation occurring at 75 Hz rate.

Specifications:

Nominal Line Voltage:	240/220/120/100 V
Input Current at Max Output Power:	240/230/220V: 1.5A 120/100V: 3.3A
Width and Height:	9.25" x 5" x 13.25" (23.5cm x 1.7cm x 33.7cm)
Weight:	20 lbs (9.07 kg)

Output Characteristics:

Mode	Output Wave-form	Max Power	Activation
CUT	4.0 MHz CW sinusoid	120 W at 500 Ohms	Footswitch or fingerswitch
CUT/COAG	4.0 MHz with rectified full wave envelope	90 W at 500 Ohms	Footswitch or fingerswitch
HEMO	4.0 MHz with square wave rectified envelope	60 W at 500 Ohms	Footswitch or fingerswitch
BIPOLAR HEMO	1.7 MHz with square wave rectified envelope	40W at 200 Ohms	Footswitch
BIPOLAR TURBO	1.7 MHz with CW sinusoid	120W at 200 Ohms	Footswitch

Intended Use [21 CFR 807.92(a)(5)]

Orthopedic, arthroscopic, spinal, and neurosurgical

For resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal and neurological procedures. For soft tissue resection and ablation during arthroscopic surgical procedures of knee, shoulder, ankle, elbow, hip and wrist.

Cutting

Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags, Blepharoplasty.

Blended Cutting and Coagulation

Snoring, Submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage, skin tags, papilloma Keloids, Keratosis, Verrucae, Basal CellCarcinoma, Nevi, Fistulas, Epithelioma, Cosmetic Repairs, Cysts, Abscesses, Development of skin flaps.

Hemostasis and Nonablative Coagulation

Control of bleeding, Epilation, Telangiectasia

Bipolar

Pinpoint, Precise Coagulation, Pinpoint Hemostasis, in any field (wet or dry), snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, and turbinate shrinkage.

Technological Characteristics [21 CFR 807.92(a)(6)]

Elliquence LLC believes that the subject device has the identical technological characteristics of the predicate device. This include outputs, performance, software, electronics, and indications for use. We believe the subject device is substantially equivalent to the predicate device.

Performance Data [21 CFR 807.92(b)(1)]

The Ellman SurgiMax / SurgiMax Plus complies with IEC 60601-1 and IEC 60601-2-2. Non-clinical testing and comparison between the subject device and predicate device demonstrate equivalent performance.

Predicate Device [21 CFR 807.92(a)(3)]

The predicate devices are listed as follows:

- Ellman Surgimax – K061174

The subject device and predicate device have identical indications for use, waveforms, functionality with bipolar and monopolar devices, frequency, maximum power, weight, and power adjustment. The electronics and software in the subject device is the same identical electronics and software in the predicate device. The outputs and performance characteristics are identical as the electronics and software have not changed.

The differences are:

- Cosmetic differences to the outer case and faceplate
- Difference in product name (Elliquence Surgimax or Elliquence Surgimax Plus versus Ellman Surgimax)
- Labeling changed to reflect the company name and the image to reflect the cosmetic differences.

These differences do not affect safety or performance as they are cosmetic or aesthetic in nature.

Conclusion [21 CFR 807.92(b)(3)]

We believe the differences between the subject device and predicate device are minor and conclude that the subject devices are as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Elliquence, LLC.
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Shelton, Connecticut 06484

AUG 25 2010

Re: K100390
Trade Name: Eliquence Surgimax / Surgimax Plus
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: July 20, 2010
Received: July 22, 2010

Dear Mr. Azary:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K100390

510(k) Number (if known):

Device Name: Elliquence Surgimax / Surgimax Plus

Indications For Use:

Orthopedic, arthroscopic, spinal, and neurosurgical

For resection, ablation, and coagulation of soft tissues and hemostasis of blood vessels in orthopedic, arthroscopic, spinal and neurological procedures. For soft tissue resection and ablation during arthroscopic surgical procedures of knee, shoulder, ankle, elbow, hip and wrist.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K100390