JUN 2 8 2006

K061174

510 (k) Summary

Date Prepared

4/30/06 (Revised 6/25/06)

Submitter's Information

Ellman International Inc. is located at 3333 Royal Avenue, Oceanside, NY 11572.
Contact Name: Dr. Jon Garito

Establishment Registration for Ellman International Inc. is 2428235

Device Trade Or Proprietary Names

Possible device trade names are:

- Surgi-Max

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 Surgi-Max 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.

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 120 or 100 Hz rate.

HEMO – Deeply modulated wave with average to peak ratio approximately 50%. Modulation occurring at 120 or 100 Hz rate of square wave.

Output Characteristics

Mode	Output Waveform	Max Output Power	Activation
CUT	4.0 MHz CW sinusoid	120W @ 500 Ohms	Via footswitch or fingerswitch
CUT / COAG	4.0 MHz w/ rectified full wave envelope	90W @ 500 Ohms	Via footswitch or fingerswitch
HEMO	4.0 MHz w/ square wave rectified envelope	60W @ 500 Ohms	Via footswitch or fingerswitch
BIPOLAR HEMO	1.7 MHz w/ square wave rectified envelope	40W @ 200 Ohms	Via footswitch
BIPOLAR TURBO	1.7 MHz w/ modulated envelope	120W @ 200 Ohms	Via footswitch

Physical Characteristics

Size: 9" (W) x 5" (H) x 13" (D)
Weight: 18 lbs / 8.16 kg

The subject device is packaged with the following items:

- Ellman Surgi-Max Radiofrequency Generator
- Power Cord
- Footswitch & Cable
- Foot controlled Handpiece
- Bipolar Cable
- Disposable Neutral Plate
- Instruction Manual
- Fingerswitch Handpiece

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 Cell Carcinoma, 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)]

Ellman International believes that the subject device is substantially equivalent to the predicate device.

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

The Ellman Surgi-Max complies with IEC 60601-1 and IEC 60601-2-2.

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

The predicate devices are listed as follows:

- Ellman Surgitron IEC 120 / 4.0 DU – K013255

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
9200 Corporate Boulevard
Rockville MD 20850

Ellman International Inc.
% Jon Garito, Ph.D.
President
3333 Royal Avenue
Oceanside, New York 11572

JUN 28 2006

Re: K061174
Trade/Device Name: Ellman Surgi-Max
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI, HRX
Dated: April 26, 2006
Received: April 27, 2006

Dear Dr. Garito:

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.

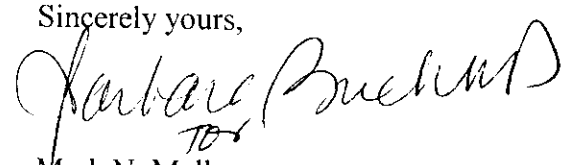
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Indications for Use

5 10(k) Number (if known): **K061174**

Device Name: Ellman Surgi-Max

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 Cell Carcinoma, Nevi, Fistulas, Epithelioma, Cosmetic Repairs, Cysts, Abscesses, Development of skin flaps.

Hemostasis and Nonablative Coagulation

Control of bleeding, Epilation, Telangiectasia

Bipolar

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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 General, Restorative,
and Neurological Devices

510(k) Number K061174