APR 7 2005

ellman international, inc. established 1959

ellman Surgitron Radiolase II
510(k) Summary

K042710

Page 1 of 2

1. Submitter name and address:

Dr. Jon. C. Garito
President
ellman international
3333 Royal Avenue
Oceanside, New York 11572-3625

2. Device name and classification:

2.1 Device Name: Surgitron Radiolase II
2.2 Classification: Class II device, 21 CFR 878.4400

3. Description of the device:

The ellman Surgitron Radiolase II is a high frequency, medium power output electrosurgical medical device. The design is similar to currently marketed ellman electrosurgical generators and provides the essential operational modes that are most often used in medium power electrosurgical applications. The unit consists of both a nominal 50 Watt maximum output power in monopolar mode and a nominal 55 Watt maximum output power in bipolar mode, providing the capability of precision cutting, coagulation, and hemostasis in a four megacycle frequency electrical current. The unit is designed to comply with the international safety standards.

4. The intended use/indication for use of the device:

4.1 Cutting
Skin Incisions, Biopsy, Cysts, Abscesses, Tumors, Cosmetic Repairs, Development of Skin Flaps, SkinTags, Nevi, Keratosis, Oculoplastic Procedures, Blepharoplasty, Aponeurotic Repair, Levator Resection, Arthroscopic Procedures

4.2 Blended Cutting and Coagulation
Skin Tags, Papilloma Keloids, Keratosis, Verrucae, Basal Cell Carcinoma, Nevi, Fistulas, Epithelioma, Cosmetic Repairs, Cysts, Abscesses, Development of Skin Flaps, Oculoplastic Procedures, Arthroscopic Procedures, ENT procedures

4.3 Hemostasis
Control of Bleeding, Epilation, Telangiectasia

4.4 Bipolar
Pinpoint, Precise Cutting and Coagulation, Pinpoint Hemostasis in any field (Wet or Dry)

3333 Royal Avenue
Oceanside, NY 11572-3625 U.S.A.
Tel: (800) 835-5355 • (516) 594-3333
www.ellman.com

5. Identification to predicate devices

5.1.Sugitron Radiolase with general use indication K992382
5.2 Surgitron 4.0 Dual RF/120 IEC with general use indication K013225

Page 2 of 2

6. Summary of the technological characteristics of the new device in comparison to the predicate devices.

Substantial equivalence
In Technological Characteristics comparison

FEATURE	ellman SURGITRON RADIOLASE II (New Application Device)	ellman SURGITRON RADIOLASE K992382 PREDICATE	ellman SURGITRON 4.0 Dual RF/120 IEC K013225 PREDICATE
Indications For Use	Monopolar and /or Bipolar Electrosurgical Cutting, Blended Cutting and Coagulation, and Hemostasis Refer to Page 5 for more specific indications for use	Monopolar- covers all indications for use as the Surgitron Radiolase II device. Refer to Exhibit D	Monopolar-covers many indications for use listed for Surgitron Radiolase II device. Bipolar- covers all indications of use listed for Surgitron Radiolase II device. Refer to Exhibit D
Design Specification	IEC 60601-1 and 60601-2-2 Requirementrs of the Medical Device Directive 93/42/EEC	Same As New Device	UL544 and IEC 601-2-2
Enclosure Size (inches)	10.3" wide x 4.5" high x 10.5" deep	7.0" wide x 4.3" high x 9.0" deep	9.3" wide x 5.0" high x 13.5" deep
Output Energy	Monopolar - 50 Watts Bipolar - 55 Watts	Monopolar- 50 Watts	Monopolar - 120 Watts Bipolar - 120 Watts
Output Waveform (s)	Monopolar and Bipolar- 4.0 MHz Sine-wave shaped, Fully Rectified, Partially Rectified.	Monopolar- 4.0 MHz Sine-wave shaped, Fully Rectified, Partially Rectified.	Monopolar- 4.0 MHz Sine-wave shaped, Fully Rectified, Partially Rectified Bipolar- 1.7 MHz with modulated waveform.
Software	Device does not contain software	Device does not contain software	Device contains operational software
Standards Met	IEC 60601-1, 60601-2-2 BS 5724-1	IEC 60601-1, 60601-2-2 BS 5724: Section 2.2 UL2601	IEC 601-1, 601-2-2 BS 5724: Section 2.2 UL2601
Delivery system and configuration	Monopolar and Bipolar	Monopolar	Monopolar and Bipolar
Biocompatibility Test	Not applicable	Not applicable	Not applicable
Sterilization Method(s)	Not applicable	Not applicable	Not applicable

3333 Royal Avenue
Oceanside, NY 11572-3625 U.S.A.
Tel: (800) 835-5355 • (516) 594-3333
www.ellman.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 7 2005

Mr. Jon Garito
Ellman International, Inc.
3333 Royal Avenue
Oceanside, New York 11572-3625

Re: K042710
Trade/Device Name: Surgitron Radiolase II
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: February 10, 2005
Received: February 11, 2005

Dear Mr. 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) 276-0120 . 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K042710

Device Name: SURGITRON RADIOLASE II

Indication For Use: is idendical to the Surgitron as a preamendment device such as:

* **Cutting**
  Skin and Mucosal Incisions, Biopsy, Cysts, Abscesses, Tumors, Cosmetic Repairs, Development of Skin Flaps, Skin Tags, Nevi, Keratosis, Oculoplastic Procedures, Blepharoplasty, Aponeurotic Repair, Levator Resection, Arthroscopic Procedures

* **Blended Cutting and Coagulation**
  Skin Tags, Papilloma Keloids, Keratosis, Verrucae, Basal Cell Carcinoma, Nevi, Fistulas, Epithelioma, Cosmetic Repairs, Cysts, Abscesses, Development of Skin Flaps, Oculoplastic Procedures, Arthroscopic Procedures, ENT procedures

* **Hemostasis**
  Control of Bleeding, Epilation, Telangiectasia

* **Bipolar**
  Pinpoint, Precise Cutting and Coagulation, Pinpoint Hemostasis in any field (Wet or Dry)

Prescription Use ✓ OR Over-The- Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off
Office of Surgical and Restorative Devices

510(k) Number K042710