OCT 14 1999

Surgitron Radiolase
510(k) Summary

K992382

1. Submitter Name and Address:

Frank Lin, Ph.D.
Director of R&D Engineering
Ellman International
1135 Railroad Ave.
Hewlett, NY 11557

2. Device Name and Classification

2.1 Device Name: Surgitron Radiolase
2.2 Classification: Class 2 Device, 21 CFR 878.4400

3. Description of The Device

ellman Surgitron Radiolase is a high frequency, medium power output electrosurgical device. The design is unique, simple, energy efficiency, safe, and user friendly. Furthermore, it equips the essential operational modes that are most often used in electrosurgical application. The unit has a maximum 50 watt output power and provides the capability of precision cutting, coagulating, and hemostasis in four megacycle frequency electrical current. It is designed to comply with 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 CellCarcinoma, Nevi, Fistulas, Epithelioma, Cosmetic Repairs, Cysts, Abscesses, Development of Skin Flaps, Oculoplastic Procedures, Arthroscopic Procedures.

4.3. Hemostasis
Control of Bleeding, Epilation, Telangiectasia

5. Identification to predicate devices

5.1. Surgitron IEC with general use indication K980177
5.2. ERBOTOM ICC 200 with indication K933157

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

Substantial Equivalence
In Technological Characteristics Comparison

FEATURE	SURGITRON RADIOLASE (NEW)*	SURGITRON IEC WITH GENERAL USE INDICATION K980177 PREDICATE	ERBOTOM ICC 200 WITH INDICATION K933157 PREDICATE
Indications For Use	Refer to Note 1	Same As New Device	Same As New Device
Design Specification	IEC 601-1 and 601-2-2 The CE Aspects of Council Directive 93/42/EEC The Medical Device Directive	IEC 601-1 and 601-2-2 The CE Aspects of Council Directive 93/42/EEC The Medical Device Directive	UL544
Output Energy	50 Watts	100 Watts	200 Watts
Output Waveform (s)	4.0MHz Sine-shaped, Fully Rectified, Partially Rectified.	1.7MHz, Sine-shaped Fully Rectified, Partially Rectified, Fulgurating-Spark-Gap	350kHz Sine-shaped 1MHz Pulse-modulated
Monopolar/Bipolar	Monopolar	Monopolar and Bipolar	Monopolar and Bipolar
Standards Met	IEC 601-1, 601-2-2, BSI5724:Section 2.2, and UL2601	IEC 601-1, 601-2-2, BSI5724:Section 2.2, and UL2601	IEC 601-1
Biocompatibity Tests	Monopolar Electrodes identical to predicate device	Same As New Device	Same As New Device
Sterilization Method(s)	Refer to Note II	Same As New Device	Not Indicated

* There is no software component in this new device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

Mr. Frank Lin
Director of Engineering Research and Development
Ellman International, Inc.
1135 Railroad Avenue
Hewlett, New York 11557

Re: K992382
Trade Name: Surgitron Radiolase
Regulatory Class: II
Product Code: GEI
Dated: July 14, 1999
Received: July 16, 1999

Dear Mr. Lin:

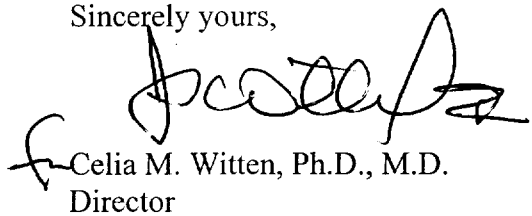
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992382

Device Name: SURGITRON RADIOLASE

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

* 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.

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

* Hemostasis
  Control of Bleeding, Epilation, Telangiectasia

(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 Devices
510(k) Number K992382

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

(Optional Format 1-2-96)