510 (k) Summary

K071343

FEB 28

Date Prepared [21 CFR 807.92(a)(1)]

[Revised] August 28, 2007

Submitter's Information [21 CFR 807.92(a)(1)]

This 510(k) is being submitted by Joseph Azary on behalf of Ellman International Inc.

Contact Information / Regulatory Consultant:
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Manufacturer / Sponsor:
Ellman International Inc.
3333 Royal Avenue
Oceanside, NY 11572.

Establishment Registration for Ellman International Inc. is 2428235

Trade Name [21 CFR 807.92(a)(2)]

Device trade name is Ace-Tip Electrodes

Device Common, Usual, or Classification Names

Electrodes, Electrosurgical Unit 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

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

The predicate devices are listed as follows:

- Ellman Electrodes – Preamendment

Description of the Device [21 CFR 807.92(a)(4)]

Ellman has been manufacturing and distributing electrodes for many years. The Ellman electrodes are used with an electrosurgical generator (such as Ellman Surgi Max K061174, Ellman Surgitron K052241). The electrical power operating at radio frequency (RF) is transferred to tissue at the surgical site. The time-varying voltage produced by the RF electrical power source yields a predetermined electrosurgical effect, such as tissue cutting or coagulation.

The Ellman family of electrodes are available in various shapes and sizes depending on the need of the surgeon.

The Ace-Tip electrodes are composed of the new noble alloy. Several of the classical Ellman electrodes are now available in the new noble alloy including:

- Loop Electrode 3mm and 5mm
- Micro Incision Needle Electrode
- Ball Electrode 2mm
- Tapered Ball Electrode 3mm
- Fine Wire Electrode
- VariTip Electrode

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

The electrodes are accessories to the Ellman electrosurgical generators for cutting of tissue and coagulation by use of high frequency electrical current.

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

The device is substantially equivalent to the predicate device based on a comparison on physical and performance characteristics.

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

The subject device is composed of biocompatible materials, has passed dielectric testing, and performs similarly to the predicate device.

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

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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 28 2008

Ellman International, Inc.
% Azary Technologies, LLC
Mr. Joseph M. Azary
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K071343
Trade/Device Name: Ellman Ace Tip Electrodes
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: January 25, 2008
Received: February 6, 2008

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.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

Enclosure

K071343

Indications for Use

5 10(k) Number (if known):

Device Name: Ellman Ace Tip Electrodes

The electrodes are accessories to the Ellman electrosurgical generators for cutting of tissue and coagulation by use of high frequency electrical current.

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)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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