K082834

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510(k) Summary

MAY - 7 2009

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

8/11/08

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

Mr. Rick Epstein
President & CEO
Ellman International Inc.
3333 Royal Avenue Oceanside, NY 11572.

Telephone: 516-267-6700

The establishment registration number for Ellman International is 2428235.

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

Trade Name

Surgitron

Device Common. Usual. or Classification Names

Electrosurgical Unit and Accessories, Electrosurgical Cutting and Coagulation and Accessories

Classification Panel

Classification of this device is at the discretion of the Center for Devices and Radiological Health (CDRH) and is presumed to be the Division of General, Restorative and Neurological Devices.

Class

Classification: Class II
Product Code: GEI, 21 CFR 878.4400

Description of the Device 121 CFR 807.92(a)(4)]

The subject device is the same device that was authorized for use under 510(k) premarket notification K013255. The purpose of this submission is to add the indications for use of "non-ablative technique" used for the treatment of mild to moderate facial wrinkles and rhytids.

The Ellman Surgitron is a compact source of high power RF energy to be employed for a variety of radiosurgical procedures. This action is achieved by front panel selection of waveforms and power levels. All selections are activated by push buttons with lights that give the operator feedback of operative status.

The power level for each mode is indicated by the front panel digital display, which also identifies the status of self-test and monitoring. This display is interlocked with the 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 provided.

The subject device is packaged with the following items:

- Ellman Surgitron IEC 120 / 4.0 DU Radiofrequency Generator
- IEC Power Cord
- Dual Footswitch & Cable
- IEC Foot controlled Handpiece
- Bipolar Cable
- Disposable Neutral Plate
- Instruction Manual
- Three Button Fingerswitch Handpiece

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

The device has the following "Indications For Use":

- Non-ablative treatment of mild to moderate facial wrinkles and rhytids for skin phototypes I-IV

The device is also indicated for:

- Cutting: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags and blepharoplasty.
- Blended Cutting and Coagulation: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin tags, papilloma keloids, keratosis, verrucae, basal cell carcinoma, nevi, fistulas, epithelioma, cosmetic repairs, cysts, abscesses, and development of skin flaps.
- Hemostasis: control of bleeding, epilation, telangiectasia.
- Fulguration: basal cell carcinoma, papilloma, cyst destruction, tumors, verrucae, hemostasis.

- 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 devices.

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

Studies comparing the subject device to the predicate device demonstrate that the subject device is safe and effective for use in non-ablative procedures such as the treatment of mild to moderate facial wrinkles and rhytids.

Predicate Device [21 CFR 807.92(a)(3)1

The predicate devices are as follows:

- Ellman Surgitron IEC 120 / 4.0 DU — K013255
- Thermage ThermaCool — K040135

The device is identical (materials, technology) to the Surgitron device in K013255. The only difference is the addition of the non-ablative indications for use.

The subject device is adding indications for use similar to the Thermage Thermacool device as found in K040135.

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

Based on the aforementioned information, the Ellman International Surgitron, with its expanded "Indication For Use" is safe and effective and substantially equivalent to the identified predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 7 2009

Ellman International, Inc.
% Mr. Rick Epstein
President & CEO
3333 Royal Avenue
Oceanside, New York 11572

Re: K082834
Trade/Device Name: Ellman International Non-Ablative Technique for Surgitron IEC
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: April 24, 2009
Received: April 29, 2009

Dear Mr. Epstein:

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 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 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 the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K082834

Device Name: Ellman International Non-Ablative Technique for Surgitron IEC

Indications For Use:

- Non-ablative treatment of mild to moderate facial wrinkles and rhytids for skin phototypes I-IV

The device is also indicated for:

- Cutting: snoring, submucosal palatal shrinkage, traditional uvulopalatoplasty (RAUP), myringotomy with effective hemorrhage control, epistaxis treatment, turbinate shrinkage, skin incisions, biopsy, cysts, abscesses, tumors, cosmetic repairs, development of skin flaps, skin tags and blepharoplasty.
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Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 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 K082834