K102698

JAN 5 2011

**510(k) Summary**

**General Information**

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| Date Prepared | 10/25/2010 |
| Classification | Class II, CFR 878.4400<br>Product Code GEI |
| Common Name | Electrosurgical, cutting & coagulation & accessories |
| Trade Name | Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System |
| Submitter | Ellman International<br>3333 Royal Ave<br>Oceanside, NY 11572 |
| Contact Information | Mr. Jonathan Achenbach<br>Sr. Dir. R&D, Clinical & Regulatory Affairs<br>Ph: 516-594-3333<br>Fax: 516-267-6750 |

**Intended Use**
The Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System is intended for non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin phototypes I-IV.

**Predicate Devices**
Ellman Non Ablative Wrinkle Treatment System (K082834, K102368, K101967) manufactured by Ellman International

**Technological Characteristics**
The device is a hand-held, non-ablative wrinkle treatment handpiece available with various size electrode end effectors and a detachable cord. The electrode is spring mounted into the handle. All materials used in the manufacture of the device are suitable for the use in the device and are the same materials used in the predicate product. As with the predicated device, the device is activated using a hand or footswitch based on user preference and is intended for use with the Ellman Radio-Frequency generators (K082834) labeled for the treatment of wrinkles and rhytides.

**Substantial Equivalence**
The Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System is as safe and effective as the Ellman Non Ablative Wrinkle Treatment System. The Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System has the same indication for use, technological characteristics, and principles of operation as its predicate device. The minor technological improvements made to the device from the previous generation predicate device do not alter the fundamental scientific

technology of the device and raise no new issues of safety or effectiveness. Thus, the Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System is substantially equivalent.

**Performance Data**

All appropriate testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests. In all instances, the Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System functioned as intended and in conformance with anticipated results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ellman International Inc.
% Mr. Jonathan Achenbach
3333 Royal Ave.
Oceanside, NY 11572

Re: K102698
Trade Name: Pellevé Glidesafe Non-Ablative Wrinkle Treatment System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 29, 2010
Received: January 3, 2011

Dear Mr. Achenbach:

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 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); 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

Ellman International

**"INDICATIONS FOR USE"**
**Statement**

510(k) Number (if known): K102698

Device Name: Pellevé GlideSafe™ Non-Ablative Wrinkle Treatment System

The Device has the following "Indications for Use":

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

Prescription Use ___X___ OR Over-The Counter Use_____

(per 21 CFR 801.109)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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