K132665

510(K) Summary

This 510(K) Summary of safety and effectiveness for the Pellevé Non-Ablative Wrinkle Treatment System is submitted in accordance with the requirements of the SMDA 1990 and FDA guidance concerning the organization and content of a 510(K) summary.

Applicant:	Ellman International
Address:	Ellman International 400 Karin Lane Hicksville, NY 11801
Contact Person:	Alison Sathe
Telephone:	513-658-8960 asathe@ellman.com
Preparation Date:	August 21, 2013
Device Trade Name:	Pellevé Non-Ablative Wrinkle Treatment System
Common Name:	Electrosurgical, cutting & coagulation & accessories
Classification Name:	Electrosurgical, cutting & coagulation & accessories GEI. 878.4400
Legally Marketed Predicate Device(s):	Pellevé Non-Ablative Wrinkle Treatment System

SEP 25 2013

Device Description:
The device is a hand-held, non-ablative wrinkle treatment handpiece available with various size electrode end effectors and a detachable cable. The device is activated using a hand or footswitch based on user preference and is used with the Ellman radiofrequency generators labeled for the treatment of wrinkles and rhytides. The radiofrequency generator operates 4 mHz and is used in the CUT or PELLEVÉ mode for non-ablative wrinkle treatments.

Intended Use:
The device has been cleared pursuant to K102698 for the following Indications For Use:
Non-ablative treatment of mild to moderate facial wrinkles and rhytides for skin phototypes I-IV.

Rationale presented herein is provided to amend the indication for use to:
Non-ablative treatment of mild to moderate facial wrinkles and rhytids

The basis for this rationale is the system utilization of radiofrequency (RF) energy. RF interaction with tissue is based on impedance rather than melanin therefore skin phototype does not affect RF treatments.

Technological Characteristics:
The Pellevé Non-Ablative Wrinkle Treatment System has the same technological characteristics as the predicate device.

Performance Data:
None submitted

Substantial Equivalence:
The Pellevé Non-Ablative Wrinkle Treatment System has the same principles of operation and technological characteristics as the predicate. The modification of the indications for use raises no new issues of safety or effectiveness. Thus, Pellevé Non-Ablative Wrinkle Treatment System is substantially equivalent to the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Ellman International, Incorporated
Ms. Alison Sathe
Director of Regulatory and Clinical Affairs
400 Karin Lane
Hicksville, New York 11801

September 25, 2013

Re: K132665
Trade/Device Name: Pellevé 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: August 23, 2013
Received: September 3, 2013

Dear Ms. Sathe:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

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 contact 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. 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,

Neil R Ogden -S
2013.10.16 12:37:17 -04'00'

For Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132665

Device Name: Pellevé Non-Ablative Wrinkle Treatment System

Indications for Use:

The Pellevé Non-Ablative Wrinkle Treatment System is indicated for the non-ablative treatment of mild to moderate facial wrinkles and rhytids.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Long H. Chen -A

Digitally signed by Long H. Chen -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056
Date: 2013.09.24 15:01:54 -04'00'

(Division Sign-off) For MXM
Division of Surgical Devices
510(k) Number K132665