SEP 10 1999

K992630

Jennifer MAXX
150 Fifth Avenue
New York, NY 10010
212 645 9212

SUMMARY OF SAFETY AND EFFECTIVENESS

A. SPONSOR IDENTIFICATION:

Jennifer Maxx, Inc.
150 Fifth Avenue, Suite 218
New York City, NY 10011
Telephone: 212 645-9212

B. ESTABLISHMENT REGISTRATION NUMBER: Pending

C. OFFICIAL CONTACT PERSON

Norman F. Estrin, Ph. D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac , MD 20854
Tel. : (301) 279 -2899
Fax : (301) 294-0126

D. DATE OF PREPARATION OF THIS SUMMARY: September 2, 1999

E. PROPRIETARY (TRADE) NAME: THERMALIGHT®® 2000

F. COMMON NAME: Epilator

G. CLASSIFICATION NAME AND REFERENCE : Unclassified

H. PROPOSED REGULATORY CLASS:

I. DEVICE PRODUCT CODE:

J. PANEL: General & Plastic Surgery

K. DESCRIPTION OF DEVICE:

The Thermalight2000 is an instrument which is designed to painlessly, safely, and effectively remove hair by the application of pulsed light energy to the hair follicle. It operates similar to needle electrolysis machine in that it removes hair, one hair at a time by thermolysis. Using the Thermalight2000, thermolysis is achieved by the application of light energy to the hair growth support tissue instead of the application of electrical energy employed by conventional needle electrolysis units.

L. INTENDED USE:

The **THERMALIGHT®® 2000** is intended to destroy the dermal papilla of a hair.

M. INDICATIONS FOR USE:

The **THERMALIGHT®® 2000** is indicated for removal of unwanted body hair through the application of pulsed light energy applied to the hair follicle at the surface of the skin (non-invasive photo-epilation).

N. PREDICATE DEVICE:

The **THERMALIGHT®® 2000** is substantially equivalent to the D''Plume XXII Photocoagulator (Epilation Machine) (K895687)

O. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS:

Both the **THERMALIGHT®® 2000** and the D''Plume XXII Photocoagulator (Epilation Machine) (K895687) have the same intended use and both are indicated for removal of unwanted body hair through the application of pulsed light energy applied to the hair follicle at the surface of the skin (non-invasive photo-epilation).The **THERMALIGHT®® 2000** treats one hair at a time just as does conventional needle electrolysis and as does the D''Plume XXII Photocoagulator. Both machines employ a power supply to charge an energy storage device, feeding a xenon pulsed light source to produce a visible light energy pulse. Both machines also employ an optical fiber to conduct the light from the xenon flash lamp to the surface of the skin. The energy delivered to the skin surface is identical and the usage of the two units are identical. The **THERMALIGHT®® 2000** incorporates more modern design techniques and newer components which provide a more reliable unit, with more economical, and more consistent performance.

P. SAFETY:

Unlike the machines which treat large areas at a time, the **THERMALIGHT®® 2000** is safe and can not generate enough power to damage the skin. The light energy is applied by means of a optical fiber tip which is placed at the entrance to the hair follicle. The tip never enters below the skin. There is no pain, no skin damage, and there is no risk of introducing disease.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Jennifer Maxx, Inc.
c/o Norman F. Estrin, Ph.D., RAC
President
Estrin Consulting Group, Inc.
9109 Copenhaver Drive
Potomac, Maryland 20854

Re: K992630
Trade Name: Thermalight 2000
Regulatory Class: II
Product Code: GEX and KNW
Dated: June 14, 1999
Received: June 15, 1999

Dear Dr. Estrin:

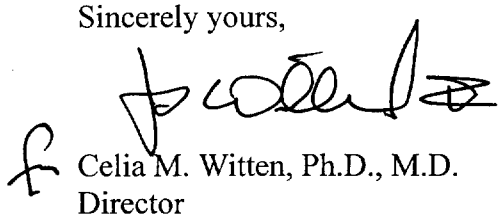
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



for 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

CONFIDENTIAL

510(k) Number: **K992630**

Device Name: **THERMALIGHT 2000**

Indications for Use:

The **THERMALIGHT 2000** is indicated for removal of unwanted body hair through the application of pulsed light energy applied to the hair follicle at the surface of the skin (non-invasive photo-epilation).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-the-Counter Use
(Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992630