K093168

MAY 21 2010

510(k) Summary

SPONSOR **807.92(a)(1)**

Company Name: DERMEO

Company Address: Vap 18, 189 Rue d'Aubervilliers
Paris, France 75018

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Contact Person: PASCALE TANNOUS

Summary Preparation Date: May 6, 2010

DEVICE NAME **807.92(a)(2)**

Trade Name: MEDIFLASH3 and ESTEFLASH3
Common/Usual Name: Intense Pulsed Light System
Classification Name: Powered Laser Surgical Instrument
Regulation Number: 878.4810
Product Code: GEX
Device Class: II

PREDICATE DEVICE **807.92(a)(3)**

Legally Marketed Equivalent Device

Company	*Product*	*510(k) #*
McCue Plc	McCue Energist Ultra Variable Pulsed Light	K060234

DEVICE DESCRIPTION **807.92(a)(4)**

The MEDIFLASH3 and ESTHEFLASH3 Intense Pulsed Light Device Systems are light based medical devices that deliver a flash of pulsed non-ionizing radiation within the spectral range covering 400 to 1200 nanometers. The system is designed to be compact and self contained and includes the following features:

- Control console unit
- Display panel
- Power supply
- Cooling system
- Hand piece with detachable cartridge with lamp, mirror and filter

DEVICE INTENDED USE **807.92(a)(5)**The

The MEDIFLASH3 Intense Pulsed Light device is indicated for use in medical and aesthetic applications requiring selective photothermolysis for dermatological and medical aesthetic treatments as follows:

Intense Pulsed Light Energy/Wavelengths (420nm-1200nm)

- The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, melasma, angiomas and spider angiomas, poikiloderma of Civatte, leg veins, facial veins and venous malformations for Fitzpatrick Skin types I-III (Wavelengths – 515 – 1200 nm, or 500 – 600 and 870 – 1200nm)
- The treatment of benign pigmented epidermal and cutaneous lesions including scars and striae for Fitzpatrick Skin types I-III (Wavelengths -550- 1200 nm)
- Treatment of inflammatory acne (acne vulgaris) for Fitzpatrick Skin types I-III (Wavelengths 420 – 1200 nm)
- Removal of unwanted hair from all skin types and to effect stable long term or permanent* hair reduction through selective targeting of melanin in hair follicles. (Light skin for Fitzpatrick Skin types I-IV Wavelengths - 620 – 1200 nm, Dark Skin for Fitzpatrick Skin types IV and V 690 – 1200 nm). MEDIFLASH3 cannot be used for skin type VI.

*Permanent hair reduction is defined as a long term stable reduction in the number of hairs regrowing after a treatment regime.

The ESTHEFLASH3 Intense Pulsed Light device is indicated for use in medical and aesthetic applications requiring selective photothermolysis for dermatological and medical aesthetic treatments as follows:

- Removal of unwanted hair from all skin types and to effect stable long term or permanent* hair reduction through selective targeting of melanin in hair follicles. (Light skin for Fitzpatrick Skin types I-IV Wavelengths - 620 – 1200 nm, Dark Skin for Fitzpatrick Skin types IV and V 690 – 1200 nm). ESTHEFLASH 3 cannot be used for skin type VI.

*Permanent hair reduction is defined as a long term stable reduction in the number of hairs regrowing after a treatment regime.

COMPARISON OF TECHNICAL CHARACTERISTICS 807.92(a)(6)

Parameter	Dermeo MEDIFLASH3 and ESTHEFLASH3	Energist Ultra
Intended use	Treatment of acne, vascular and pigmented lesions and hair removal for MEDIFLASH, hair removal only for ESTHEFLASH	Treatment of acne, vascular and pigmented lesions and hair removal.
Design	• Control console unit • Display panel	• Control console unit • Display panel

	• Power supply • Cooling system • Handpiece with detachable cartridge with lamp, mirror and filter	• Power supply • Cooling system • Handpiece w/ integrated switch, lamp, filter and glass coupling block
System Type	Intense Pulse Light System	Intense Pulse Light System
Power supply	120V	100V to 240V
Frequency of electrical current	50-60Hz	60/50hz
No of handpieces	1	2

NONCLINICAL AND CLINICAL TEST **807.92(b)**

Testing of the Dermeo device was performed to UL 60101-1 -electrical safety and FCC 60601-1-2 – Electro-compatibility standards. Performance data was provided to demonstrate that the system is capable of providing the outputs necessary to achieve its required treatment parameters.

CONCLUSION **807.92(b)(3)**

The MEDIFLASH 3 and ESTHEFLASH 3 are substantially equivalent to the predicate device in intended use, design, mode of operation and performance characteristics

The MEDIFLASH 3 and ESTHEFLASH 3 introduce no new questions concerning the safety or effectiveness and is thus substantially equivalent to the predicate devices

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

MAY 21 2010

Dermeo
% Smith Associates
E. J. Smith
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K093168
Trade/Device Name: MEDIFLASH3 AND ESTHEFLASH3 Intense Pulsed Light System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: May 18, 2010
Received: May 18, 2010

Dear E. J. Smith:

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 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

Indications for Use

510(k) Number (if known): K093168

Device Name: MEDIFLASH3 and ESTHEFLASH3 Intense Pulsed Light System

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

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

510(k) Number K093168

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark RP Ogden for mkm

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

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