510(k) SUMMARY

Or-Light®
YPERION dermatologic Intense Pulsed Light system

Submitter's name, address, telephone number, contact person and Date

YPERION Technology SAS
76-78 Av des Champs Elysées
75008 Paris
France
Telephone : 00 33 1 56 89 10 40
Fax : 00 33 1 45 27 68 33

OCT - 7 2009

Contact person : Pascal Danet
General Manager
2, rue Beethoven
75016 Paris
France
Telephone : 00 33 1 56 89 10 40
Fax : 00 33 1 45 27 68 33
Email : pdanet@yperion.fr

Date prepared: February 26, 2009

Name of Device

Device Trade Name: Or-Light® System
Model: YPL08011
Common use: Intense Pulsed light System for cosmetic and dermatologic treatments
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Product code : GEX
Regulation Number : 878 4810

Predicated device

Yperion Technology : L600®; K030480
Danish Dermatologic Developpement (as DDD) : Ellipse I²PL ; K060516

System Description

The Or-Light® is a non-coherent light based device intended to carry out dermatologic and aesthetic care on patients by skin professional.
The system consists of a console containing a power unit controlled by electronic and software. Setting is selected by the operator through a display panel (touch screen).
Light energy for the treatment is generated by the applicators connected to the device. Two type of applicator can be connected, one at a time. The applicators are in the waveband of

- 400 nm – 1000 nm
- 610 nm – 1000 nm.

The applicator is cooled by a closed water cooling circuit built in the device.

Intended Use

The Or-Light® is designed to perform :

- Hair Removal for skintype I to IV
- Benign pigmentary lesions for skintype I to III
- Benign vascular lesions for skintype I to III
- Treatment of inflammatory Acne for skintype I to III

Comparing technical characteristics/ Performance Data

The differences in the specification of the Or-Light® and the predicate devices do not result in different performances or raise any new question of safety or effectiveness. The clinical data demonstrate that the device can be used effectively and safely by a trained skin professionnal.

Summary

Based on the foregoing, we believe that the Or-Light® is substantially equivalent to the legally marketed predicate devices, the L600® and the Ellipse I²PL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

YPERION Technology
% Pascal Danet
General Manager
2, rue Beethoven
75016 Paris
France

OCT - 7 2009

Re: K090724
Trade/Device Name: System Or-Light®
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: September 18, 2009
Received: September 22, 2009

Dear Pascal Danet:

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.

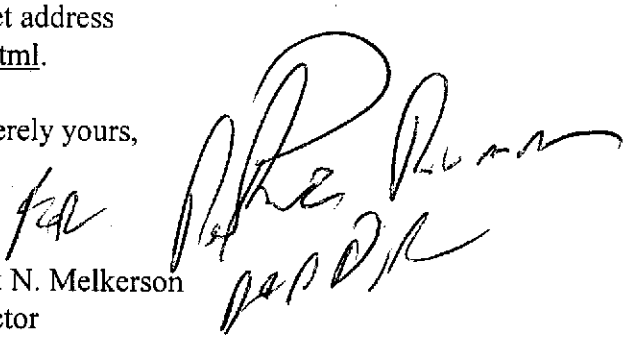
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

Indication for use

Applicant : YPERION TECHNOLOGY SAS

510(k) Number (if known): K090724

Device Name: System Or-Light®

Indications of Use:

The Or-Light® is a non-coherent light-based device intended to carry out dermatologic and aesthetic care. It is meant to be handled by competent professionals trained in intense pulsed light technology.
Two different applicators can be used on the Or-Light® device.

The HR applicator (610-1000 nm) is indicated for:

- Hair Removal for skintype I to IV

The SR applicator (400-1000 nm) is indicated for

- Benign pigmentary lesions for skintype I to III
- Benign vascular lesions for skintype I to III
- Inflammatory acne treatment for skintype I to III

Prescription Use ____X____ And/Or Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K090724