K091125
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SEP 3 2010

510(k) Summary

Submitter

Verilux 340 Mad River Park, Ste 1 Waitsfield, VT 05673 1-886-544-4865

Contact

Ryan Douglas MFG Solutions 1259 Willow Lake Blvd St. Paul, MN 55075 Phone: 651-203-2100: Fax: 651-203-2110

Submission Date: April 15, 2009

Trade Name: ClearWave® Phototherapy System for Acne (CWST2)

Common Name: ClearWave® Phototherapy System

Classification Name: Laser surgical instrument for use in plastic surgery and Dermatology

Classification Panel: General and Plastic Surgery (21 CFR 878.4810, Product Code GEX, Panel 79)

Substantial Equivalence:

The ClearWave® Phototherapy System for Acne is substantially equivalent to the Tanda Skincare System (K080591). The intended use and technological characteristics of the ClearWave® Phototherapy System for Acne are similar to the intended use and technological characteristics of the listed predicate device. Differences between the ClearWave® Phototherapy System for Acne and the predicate device do not introduce new risks.

Device Description:

The ClearWave® Phototherapy System for Acne is a hand held light device which emits a low intensity of blue light at a wavelength of 414 ± 10 nm in the visible range of the spectrum. The head is programmed with a timed treatment cycle. The light modules are contained in the changeable head of a hand held device. The ClearWave® Phototherapy System for Acne is small and light weight which allows for easy handling and mobility.

Intended Use:

The ClearWave® Phototherapy System for Acne is designed for Over-the-Counter use. ClearWave® provides phototherapeutic light for the treatment of dermatological conditions in the convenience of a consumer's home. The target population for the ClearWave® Phototherapy System for Acne is the same as that for the predicate device, Tanda Skincare System.

Indication for Use:

The ClearWave Phototherapy System for Acne provides phototherapeutic blue light to treat mild to moderate inflammatory acne.

Technological Characteristics

Data obtained through spectral testing indicates that the irradiance of the ClearWave® Phototherapy System for Acne at a practicable distance from the skin surface (3.5mm) is comparable with the cited predicate device. The technology, mode of operation, and general principles for treatment with this device are the same as the predicate device.

Performance Testing

The ClearWave® Phototherapy System for Acne complies with UL 60601-1 (Medical Electrical Equipment: Particular requirements for basic safety) and EN 60601-1-2 (Electromagnetic Compatibility). Analysis of the material has demonstrated compliance to ISO 10993 (Biocompatibility). Usability testing has show suitability for OTC-labeling. Spectral testing and other verification/validation testing confirmed performance of hardware and software to requirements.

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

Verilux
% MFG Solutions, Inc.
Mr. Ryan Douglas
1259 Willow Lake Boulevard
St. Paul, Minnesota 55110

SEP 3 2010

Re: K091125
Trade/Device Name: ClearWave Phototherapy System for Acne
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: ONE
Dated: August 24, 2010
Received: August 26, 2010

Dear Mr. Douglas:

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.

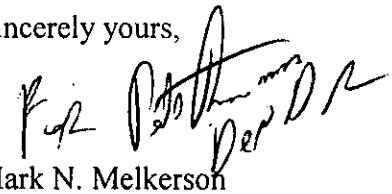
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

K091125

Indications for Use

SEP 3 2010

510(k) Number (if known): K091125

Device Name: ClearWave Phototherapy System for Acne

The ClearWave Phototherapy System for Acne provides phototherapeutic blue light to treat mild to moderate inflammatory acne.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use x (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 K091125