K120560
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510(k) Summary
Trinity Wrinkle Remover

NOV 6 2012

Prepared: February 17, 2012

CONTACT INFORMATION

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Contact Person: Tera Valdez, Vice President

DEVICE NAME

Trade Name: Trinity Wrinkle Remover
Common Name: Light based over the counter wrinkle reduction device
Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product Code: OHS

PREDICATE DEVICE

The Carol Cole Company is claiming substantial equivalence to the following device:
Light for Wrinkles device, cleared under 510(k) K101190 and K120775

a. Device Proprietary Name: Light for Wrinkles
b. Manufacturer: LED Intellectual Properties, LLC
c. Product Code: OHS
d. Indications for Use: The Light for Wrinkles is an over-the-counter hand-held device intended for the use in the treatment of full-face wrinkles

The Trinity Wrinkle Remover is a new device design based on portions of the NuFACE® Trinity Facial Toning Device, which was cleared under K103472. The main body of the NuFACE® Trinity Facial Toning Device is used in conjunction with a new Treatment Head, that emits energy in the Red and IR region of the spectrum for reducing fine lines and wrinkles.

INDICATIONS FOR USE/INTENDED USE

The Trinity Wrinkle Remover is an over-the-counter hand-held device intended for the use in the treatment of full-face wrinkles.

TECHNOLOGICAL CHARACTERISTICS

The Trinity Wrinkle Remover is as an over-the-counter phototherapy device for the reduction of fine lines and wrinkles. It emits energy in the red and IR regions of the spectrum to reduce fine lines and wrinkles.

The device measures 3" W x 5.25" L x 1.25" D. Its outer case is injection molded of thermoplastic resin. The detachable Treatment Head comprises (36) Light Emitting Diodes (LED's) which emit light at 632nm and 820nm. The device is powered by 4

rechargeable batteries. The Trinity Wrinkle Remover comes with a Charging Cradle, which measures 3.25" W x 4" L x 3.25" D, to charge the internal batteries when not in use. The Charging Cradle is powered d.c. power from a pre-approved wall-mount Power Supply provided with the device. All charging circuitry is contained within the handheld unit itself.

The Trinity Wrinkle Remover Treatment Head is designed for optimal contact with the face. The device continually pulses the LEDs output, and provides a fixed output intensity level.

An ascending sequence of audible beeps informs the User the device is ready for use. When the user turns off the device, a descending audible tone is emitted.

To promote proper use, an audible beep informs the user to relocate the device to treat a new location on the skin. The device has a fixed LED output intensity.

COMPLIANCE DATA

The Trinity Wrinkle Remover was tested and found to conform to International Standard IEC 62471:2006 for the Photobiological safety of lamps and lamp systems.

The Trinity Wrinkle Remover was also tested and found to be in compliance with IEC 60601-1-2 for Electromagnetic Compatibility (EMC). The Trinity Wrinkle Remover was evaluated and found to be in compliance with IEC 60601-1 for Electrical Safety.

SUBSTANTIAL EQUIVALENCE

The Trinity Wrinkle Remover has the same intended use and indications for use as the predicate device. The Trinity Wrinkle Remover emits Red and IR energy at the same wavelengths and intensities as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

Carol Cole Company
% Bob Duffy Associates, Incorporated
Mr. Bob Duffy
President
16405 Summer Sage Road
Poway, California 92064

November 6, 2012

Re: K120560
Trade/Device Name: Trinity Wrinkle Remover
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: OHS
Dated: October 28, 2012
Received: October 31, 2012

Dear Mr. Duffy:

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,

Peter D. Rumm -S

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): K120560

Device Name: Trinity Wrinkle Remover

Indications For Use:
The Trinity Wrinkle Remover is an over-the-counter hand-held device intended for the use in the treatment of full-face wrinkles.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ AND/OR
(Part 21 CFR 801 Subpart D)

Over-The-Counter Use ___X___
(21 CFR 801 Subpart C)

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

510(k) Number K120560