JUN 17 2014

K132833

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Number:

Applicant Information:

Owner Name:	Accord Media
Address:	307 Seventh Avenue, Suite 2302 New York, NY 10001
Contact Person:	Marta Wohrle
Phone Number:	917-640-8111
Date Prepared:	June 16, 2014

Device Information:

Classification:	Class II
Trade Name:	Ultra Renew Plus
Common name:	Facial Toning Device
Classification name:	Over-The-Counter Powered Light Based Laser for Acne (21 CFR 878.4810/OLP) Light Based Over the Counter Wrinkle Reduction (21 CFR 878.4810/OHS) Massager, Therapeutic, Electric (21 CFR 890.5660/ISA)

Predicate Devices:

The Accord Media Ultra Renew Plus is substantially equivalent in intended use and method of operation to the Omnilux Clear-U, the Silk'n FX, and the Ultrasonic Therapeutic Massager (KUP-300).

Device Description:

The Ultra Renew Plus is a hand held, mains powered, device used for the treatment of acne, periorbital wrinkles, and the relief of minor aches and pains. The Ultra Renew Plus combines two (2) functional modes of operation, LED and ultrasonic. The LED functional mode provides narrow bandwidth spectral output in the blue (415 ± 5 nm) and red (650 ± 5 nm) ranges. The ultrasonic functional mode operates at a fixed frequency of 3 MHz ± 5%. The Ultra Renew Plus uses a supplied power adaptor.

Intended Use:

The Accord Media Ultra Renew Plus is intended to be used:

LED functional mode

- To emit energy in the red and blue region of the spectrum, specifically to treat mild to moderate acne on the face.
- To emit energy in the red region of the spectrum for the treatment of periorbital wrinkles.

Ultrasonic functional mode

- As an electrically powered device intended for medical purposes to relieve minor aches and pains.

Non-clinical testing:

The Ultra Renew Plus was tested and shown to meet the requirements of IEC 60601-1, Electrical Safety, and IEC 60601-1-2, Electromagnetic Compatibility.

Label comprehension, self-selection and usability studies were conducted and demonstrated that the intended users of the device could successfully follow the instructions and use the device as intended. The studies were conducted in a typical retail / mall environment.

The label comprehension study was conducted by administering a questionnaire to sixty-one (61) subjects. Subjects were given adequate time to read the label and were able to refer to it throughout the testing period. The label comprehension study found that a minimum of 90% of participants correctly understood the majority of the variables tested.

The self-selection study was conducted by administering a questionnaire to sixty-one (61) subjects. Subjects were given adequate time to read the label and were able to refer to it throughout the testing period. The self-selection study found that 95% of participants self-selected correctly.

The usability study was conducted by administering a questionnaire to twenty-five (25) subjects. Subjects were able to read and refer to the instruction manual

during the testing period. The observational, open-ended and close-ended data from the usability study show that subjects understand how to use the various functions of the device based on the instruction manual. The conclusion is that participants were able to follow the instructions and use the device in a safe and effective way.

An assessment of the Ultra Renew Plus software was conducted per the FDA "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Software verification and validation was successfully conducted to demonstrate the safe functioning of the device.

The non-clinical performance data from the Ultra Renew Plus and cleared predicate devices demonstrates the Ultra Renew Plus device is as safe and effective as, and performs similarly to, the predicate devices for OTC cosmetic use.

Comparison to Predicate Device(s):

The Ultra Renew Plus has the same intended use and similar indications, technological characteristics and performance as the Omnilux Clear-U, the Silk'n FX, and the Ultrasonic Therapeutic Massager (KUP-300). The minor differences in wording for the intended use statements of the respective products does not alter the intended user or clinical effect and, therefore, the Ultra Renew Plus is substantially equivalent with respect to intended use. Technological differences between the products are related to the wavelength of the LED output. However, these differences do not present any new issues of safety or effectiveness because the primary objectives of acne treatment and wrinkle reduction are common to both products. Moreover, performance testing demonstrates that the products perform in a substantially equivalent manner.

Substantial equivalence:

Based upon the indications for use and data provided in this pre-market notification, all functional modes of the Ultra Renew Plus have been shown to be substantially equivalent to currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

June 17, 2014

Accord Media
% Mr. Michael Chibbaro
Regulatory Consultant
1390 Elwood Drive
Los Gatos, California 95032

Re: K132833
Trade/Device Name: Ultra Renew Plus
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: OLP, OHS, ISA
Dated: June 3, 2014
Received: June 4, 2014

Dear Mr. Chibbaro:

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132833

Device Name
Ultra Renew Plus

Indications for Use *(Describe)*
The Ultra Renew Plus is an over-the-counter device intended:

- To emit energy in the red and blue region of the spectrum, specifically to treat mild to moderate acne on the face
- To emit energy in the red region of the spectrum for the treatment of periorbital wrinkles.
- As an electrically powered device intended for medical purposes to relieve minor aches and pains

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Neil R Ogden -S
2014.06.17 13:57:59 -04'00'

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