DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 24, 2017

Eglobal, LLC
% Liza Burns
Principal
Liza Burns And Associates
6469g Kawaihau Rd
Kapaa, Hawaii 96746

Re: K162071
Trade/Device Name: Illumiflow Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: January 12, 2017
Received: January 23, 2017

Dear Liza Burns:

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" (21 CFR 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,

Jennifer R. Stevenson -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)*

K162071

Device Name

IllumiFlow Laser Cap

Indications for Use *(Describe)*

IllumiFlow is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa to V or females with androgenic alopecia who have Ludwig-Savin Classifications of I – II and both with Fitzpatrick Skin Phototypes I to IV.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Section 5: 510(k) Summary

Submitter/Applicant Name/510k Holder:
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Contact email: lizaburns@mlode.com

Contact person: Liza Burns

Date prepared: January 12, 2017

Trade name: illumiflow Laser Cap

Classification name: Lamp, non-heating, for promotion of hair growth

Classification: Class II (performance standards)

Product Code: OAP

Predicate Device:
Capillus 272 Pro (K143199 – original clearance for use in females; K160285 – adds treatments for males to the indications for use of all Capillus models)

Reference Devices:
iGrow-II Hair Growth System
(K140931, additional indication for use in females; K141567, original clearance for use in males)
HairMax LaserComb 82 (now sold as the HairMax LaserBand)
(K142573, hands-free version of the HairMax LaserComb for use in males and females)

Substantial Equivalence:

The illumiflow Laser Cap is substantially equivalent to the referenced predicate device based on indications for use, manufacturing materials, physical specifications, and performance specifications.

The illumiflow Laser Cap raises no safety or efficacy concerns when compared to the predicate device.

Description of the Device:

The illumiflow Laser Cap is a dome-shaped low level laser therapy (LLLT) device designed to promote hair growth in women and men by exposing the entire scalp to the photobiostimulation of 272 visible red light-emitting diodes at 650-nm and 5mW each. The cap is designed with an outer plastic cover and a protective inner liner (containing the electronics and laser array) and is powered by an included Battery Pack.

Intended Use/Indications for Use:

The illumiflow Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa to V or females with androgenic alopecia who have Ludwig-Savin Classifications of I – II and both with Fitzpatrick Skin Phototypes I to IV.

Technological Characteristics:

The illumiflow Laser Cap and the predicate Capillus272 Pro device have the following similar and substantially equivalent technological characteristics:

- *Design/Operating Principle*: Both the illumiflow Laser Cap and the predicate Capillus 272 Pro are LLLT/photobiostimulation devices (with embedded software and 272 diodes) in cap form which deliver 650-nm visible red light to the scalp in order to treat androgenic alopecia.
- *Energy Source*: Both the illumiflow Laser Cap and the predicate Capillus 272 Pro are powered by Lithium-ion battery packs. The batteries can be recharged with the provided standard AC adapters.
- *Performance*: Both the illumiflow Laser Cap and the predicate Capillus 272 Pro provide a timed 30-minute LLLT treatment.

The predicate Capillus 272 Pro is cleared as a Prescription Use device. In the case of LLLT devices, this designation does not imply that there are safety issues for unsupervised home use. The Capillus 272 Pro is designed and marketed for safe and effective home use by its intended population (males and females with androgenic alopecia). In the most recent 510(k) Summary (K160285), the Capillus 272 Pro was granted a

determination of substantial equivalence to the iGrow-II and the HairMax LaserBand, both of which are LLLT devices in Product Code OAP which are now cleared for OTC use in men and women with androgenic alopecia (iGrow-II: K140931 {OTC in females}, K141567 {OTC in males}; HairMax LaserBand 82: K142573 {OTC in males and females}).

Other minor differences between the subject and predicate devices are summarized below:

- The illumiflow Laser Cap does **not** contain a 'safety interlock' which automatically pauses therapy if the subject's head is in a less-than-optimal position.
- The illumiflow Laser Cap does **not** utilize audible tones at the beginning or end of treatment.
- The illumiflow Laser Cap is **not** available in an Extra Large size.

No new questions of safety and effectiveness have been raised as a result of these differences. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent.

Biocompatibility:

Biocompatibility tests of the patient-contacting materials (thermoplastic rubber [TPR], PETG, ABS) were conducted by BridgeMed Solutions, Inc. (Irvine, CA), based on the requirements of ISO 10993-1:2009 - Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, ISO 14971:2007 - Medical devices – Application of risk management to medical devices, FDA General Program Memorandum #G95-1, and FDA's Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

MEM Cytotoxicity test performed on the Laser Cap demonstrates that the material used in the manufacturing of the Cap is non-cytotoxic. The illumiflow Laser Cap is considered by the testing facility to have met the requirements of ISO 10993-1:2009, ISO 14971:2007, and FDA General Program Memorandum #G95-1, for surface devices with limited contact (<24 hours) with the skin and was considered safe for use.

Sensitization and irritation testing were not performed under the justification that devices utilizing identical materials are currently on the market. A biological risk assessment and full rationale for this determination is contained in the report from the testing facility.

Non-clinical Performance Testing:

Performance tests were conducted in support of the design verification of the illumiflow Laser Cap to confirm compliance to design specifications; all functions were verified to operate as designed, IlllumiFlow Laser Cap met all acceptance criteria in the performance testing.

Testing to IEC 60825-1 certifies the laser system to classification 3R, which is the same as the predicate devices. The illumiflow device was also tested and complies with Electrical Safety and EMC testing, which include the requirements of IEC 60601-1:2012 3rd Edition "Medical Electrical Equipment Part 1 – General Requirements for Safety" IEC 60601-1-2 "Medical Electrical Equipment Part 1-2, General Requirements for Safety – Collateral Standard Electromagnetic Compatibility Requirements and Tests IEC and 60601-1-11 Home healthcare medical equipment. The charger conforms to IEC 60950 and the battery to IEC 62133.

Usability Testing:

A two-part study (Study A: Labeling Comprehension; Study B: Consumer Usability) with 29 subjects was conducted in November 2016. The studies concluded that the preponderance of the lay user participants (84%) were able to make an appropriate decision as to whether or not they were candidates for device treatment based solely on exterior packaging information (an understanding of indications, contraindications, warnings and precautions), and were able to identify whether they were within any contraindicated group. Most participants were able to set up and apply the device safely and correctly according to the IFU: 90% of the participants properly set up the device for use and 83% proceeded to follow the instructions for use, as described in the interior labeling.

Conclusion:

Based on the non-clinical verification performance testing and as described above, it can be concluded that the illumiflow Laser Cap is substantially equivalent to the predicate CapillusPro 272 (K143199, K160285) with respect to intended use, principles of operation and technological characteristics. No new questions of safety and effectiveness have been raised as a result of the minor differences between the devices.