January 26, 2018

EGlobal, LLC
% Ms. Liza Burns
Liza Burns and Associates
6469 G Kawaihau Road
Kapaa, Hawaii 96746

Re: K173843
Trade/Device Name: illumiflow 148 Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 8, 2017
Received: December 18, 2017

Dear Ms. 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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173843

Device Name
illumiflow 148 Laser Cap

Indications for Use *(Describe)*
The illumiflow 148 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 Hair 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K173843

illumiflow 148 Laser Cap: Special 510(k) Summary

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Date Summary Prepared: January 26, 2018

Device Trade Name: illumiflow 148 Laser Cap

Common Name: Laser Helmet

Classification Name: Laser, Comb, Hair (Infrared lamp)

Product Code: OAP

Classification of Device: Class II (performance standards)

Classification Regulation: Title 21, Code of Federal Regulations, §Sec.890.5500. An infrared lamp is a device intended for medical purposes that emits energy at infrared frequencies (approximately 700 nanometers to 50,000 nanometers) to provide topical heating.

Predicate Devices: illumiflow 272 Laser Cap, model CSM-010 (K162071)

LaserCap 120 (K161875)

Performance Standards: FDA mandated performance standards for this device exist and are specified under 21 CFR, §1010 and §1040. These standards, including QSR requirements are followed by regulation. Voluntary standards such as UL, in-house Standard Operating

Procedures and vendor qualification procedures are in place and utilized in the production of the illumiflow 148 Laser Cap.
At the present time, the following applicable guidance documents are in effect for this device:

- Guidance on the Content and Organization of a Premarket Notification for a Medical Laser (June 1995)
- Compliance Guide for Laser Products (FDA 86-8260)
- Laser Products, Conformance with IEC 60825-1, and IEC 60601-2-22; Guidance for Industry and FDA (Laser Notice 50)

Device Description:

Similar to the original illumiflow 272 Laser Cap and the predicate LaserCap 120, the modified illumiflow 148 Laser Cap is a low-level laser therapy (LLLT) helmet device containing red, visible light diode lasers operating at 650 nanometers, designed to deliver non-thermal energy to the hair follicles used to promote hair growth via photobiostimulation of the scalp.

The illumiflow 148 Laser Cap utilizes 148 laser diodes to deliver laser stimulation to the scalp. The device is operated via a single button on the battery pack, and has an audible timer that automatically turns the lasers off after a 30-minute treatment session.

Intended Use/Indication for Use:

The illumiflow 148 Laser Cap is an over-the-counter (OTC) device intended 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 Hair Classifications of I-II and both with Fitzpatrick Skin Phototypes I to IV.

Technological Characteristics:

The modifications to the illumiflow 272 Laser Cap since its previous clearance in K162071 have resulted in the illumiflow 148 Laser Cap (Model CSM-020) and do not alter the safety or efficacy of the device. The parent/predicate device contains 272 laser diodes. The modified illumiflow 148 Laser Cap utilizes the same individual laser diodes and helmet design. The difference in the illumiflow 148 Laser Cap when compared to the illumiflow 272 Laser Cap is the number of laser diodes: the illumiflow 148 Laser Cap contains 148 diodes and the illumiflow 272 Laser Cap contains 272 laser diodes. Due to the reduced number of diodes, the 15-minute treatment option of the parent illumiflow 272 Laser Cap (which instructed the user to treat for either a 15 or 30-minute duration) has been eliminated, and the illumiflow 148 Laser Cap will only utilize a 30-minute treatment duration. Even though the dosage per treatment is reduced, over time the delivered dosage remains similar to the parent illumiflow 272 Laser Cap, as both caps are intended to be used indefinitely. The modified device is an economical version of the current illumiflow 272 Laser Cap.

Nonclinical Performance Data:

Performance Characteristics
Testing to IEC 60601-1 and 60601-1-2 confirm the device's safety and electrical compatibility.

Testing to IEC 60825-1 certifies the laser system to classification 3R, the same as the predicate device.

The charger conforms to IEC-60950.

Testing to 60601-1-11 confirms the safety of the device for use in a home use environment.

The Battery Pack conforms to IEC 62133.

Nonclinical Testing
EGlobal, LLC performed a Risk Analysis to evaluate the implications of the design changes to the illumiflow 272 Laser Cap. It was determined there was no significant change to risk and no new risks were identified with respect to the modifications which constitute the illumiflow 148 Laser Cap. All residual risks were found to be acceptable. It was concluded that the modified design could be tested in the laboratory and that no animal or new clinical data was required to show safety, efficacy or substantial equivalence to the currently cleared model.

Based on the Risk Analysis and modifications to the device, verification activities were conducted for the illumiflow 148 Laser Cap, including the same methods and tests using the same applied acceptance criteria as the previous illumiflow 272 Laser Cap. All of the testing met acceptance criteria.

Substantial Equivalence:

The illumiflow 148 Laser Cap claims substantial equivalence to the illumiflow 272 Laser Cap CSM-010 (K162071), and the LaserCap 120 (K161875); these devices are equivalent to the illumiflow 148 Laser Cap in technological characteristics as well as in the number of weekly treatments and in the case of the LaserCap 120, the reduced number of diodes. The Feature Comparison Table (below), demonstrates the similarities and minor differences between the subject device and its parent/predicate devices to determine substantial equivalence. Differences between the subject device and the predicate devices are highlighted in yellow.

Feature Comparison Table

Feature	Subject: illumiflow 148	Parent Model: illumiflow 272 (K162071)	Predicate: LaserCap 120 (K161875)
OTC/Rx	OTC	OTC	Rx
Home/Clinic	Home	Home	Home
Treatment Time	30 minutes	15 – 30 minutes	36 minutes

Treatment Schedule	Every other day (3-4 times per week)	Every other day (3-4 times per week)	Every other day (3-4 times per week)
Power Source	Li-Ion Battery	Li-Ion Battery	Li-Ion Battery
	AC Charger	AC Charger	AC Charger
Form Factor	Helmet	Helmet	Helmet
Instructions for Use	Place on head. Press power button on battery pack. Leave on until audible timer completes (at 30 minutes). Patient operated.	Place on head Press power button on battery pack. Leave on until audible timer completes (indicating 30 minutes) or until 15 minutes have elapsed. Patient operated.	Place on head Turn Power Pack switch 'on. When device emits an audible tone, indicating that therapy ended (one long beep). turn Power Pack switch 'off.' Patient operated
User Features/Input	One Button Operation Audible Timer Status LED	One Button Operation Audible Timer Status LED	One Button Operation Audible Timer Status LED: unknown
Intended use	intended 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 Hair Classifications of I-II and both with Fitzpatrick Skin Phototypes I to IV.	Same	Same
Output power (per diode)	<5mW	<5mW	<5mW
Laser Class	3R (per IEC 60825)	3R (per IEC 60825)	3R (per IEC 60825)
Number of Laser Diodes	148 Laser Diodes	272 Laser Diodes	120 Laser Diodes
Wavelength	650-nm	650-nm	650-nm
Total Laser Output	~740mW	~1360mW	~600mW
Radiant Energy/Dose per Treatment	Approx. 1.3 kJ	Same	Same

The subject illumiflow 148 Laser Cap utilizes the same design, operating principles and fundamental technology as the predicate devices.

Performance characteristics and bench testing validate the assertion that the illumiflow 148 Laser Cap is identical to the illumiflow 272 Laser Cap for the following features:

Same intended use/indications for use: Over-the-counter (OTC) device 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.

Identical laser diodes and output power per diode: No change to the output of the individual laser diodes (650-nm, ≤5mW).

Same safety ratings/laser class: Testing to IEC 60601-1 and 60601-1-2 confirm the device's safety and electrical compatibility. Testing to IEC 60825-1 certifies the laser system to classification 3R.

Same power source: Li-Ion Battery with charger

Same device design: laser helmet

Same/Similar operation by user: Place device on head.
Press power button on the battery pack.
Leave on for 15 minutes (272 model) until automatic shut-off at 20 minutes(148 and 272 models).

Same user features: Single Button Operation
Status LED
Automatic shut-off at 30 minutes

Same/Similar treatment duration: 30 minutes per session (illumiflow 148 Laser Cap); 15 to 30 minutes (illumiflow 272 Laser Cap)

Same type of materials: FDA-compliant ABS plastic

The only difference between the subject illumiflow 148 Laser Cap CSM-020 and the illumiflow 272 Laser Cap CSM-010 model is that the total delivered energy dose delivered to the scalp is reduced for the illumiflow 148 Laser Cap, due to the reduced number of laser diodes. The illumiflow 148 Laser Cap utilizes less diodes (148 diodes vs. 272 diodes in the parent illumiflow 272 device). The 'dose' of total delivered energy/cm^2 is reduced due to the reduced number of lasers in the illumiflow 148 Laser Cap. The illumiflow 148 Laser Cap increases the treatment session length to 30 minutes (vs. the 15- to 30-minute session options with the original illumiflow 272 Laser Cap), and as treatment with either Laser Helmet, or LLLT helmets in general, is understood to be of an indefinite duration, the more economical illumiflow 148 Laser Cap with its increased treatment session length delivers essentially the same efficacious energy dose as the parent illumiflow 272 Laser Cap over time.

The illumiflow 148, is also equivalent to the predicate LaserCap120 (K161875) in that it:

- Uses fewer diodes than its parent model (Laser Cap224 and Laser Cap 120 compared to illumiflow with 272 and illumiflow 148)
- Has a similar number of diodes (120) as the illumiflow 148 Laser Cap (148): a difference of only 28 diodes

- Uses the same operating principle/technology, and total laser module output (low level laser therapy with red light diode lasers, class 3R)
- Utilizes a same/similar treatment regimen (a 36-minute session, every other day, indefinitely) as the illumiflow 148 Laser Cap (30 minutes every other day, indefinitely)
- Delivers an energy dose density/fluence (~600mW)[1] which is comparable to those delivered by the illumiflow 148 Laser Cap (~740mW)[2]
- The difference of prescription use for the Laser Cap 120 does not affect the safety or efficacy of the devices, as both devices are used in a home setting for the same intended use.

Overall, although there are fewer diodes between the illumiflow 148 Laser Cap, and the LaserCap 120 device, compared to the parent/predicate, this difference is not significant with regard to safety or efficacy in achieving the device's intended use. The devices all share the same fundamental technology and intended use: red 3R low level laser light delivery devices for the treatment of androgenic alopecia in males with Norwood-Hamilton classifications IIa to V and females with Ludwig-Savin classifications I-II and both with Fitzpatrick Skin Types I-IV. Safety profiles are the same: a total laser module output within the limitation of a Class 3R laser (per IEC 60825-1), using low-level, low-hazard laser light therapy with a visible red laser and the same individual laser output (≤5mW).

The illumiflow 148 Laser Cap delivers treatments which are similar to the predicate devices and which appear to be similar in performance to other products already cleared by the FDA. The treatment regimen of 3 to 4 treatments per week (every other day) is common to devices in the OAP product code. The Low-Level Laser Therapy devices in the OAP product code also utilize a wide range of diodes for the safe and efficacious treatment of androgenic alopecia in both genders: the sponsor maintains that the difference in the number of diodes between the subject device (148), and the predicate Laser Cap (120), or even the parent/predicate device (272) does not affect safety or efficacy. They all utilize the same/similar individual laser output (≤5mW) in order to deliver appropriate treatment for androgenic alopecia.

For these reasons, the illumiflow 148 Laser Cap satisfies the FDA's substantial equivalence guidelines with respect to intended use, performance specifications and technological characteristics.

Conclusion

The illumiflow 148 Laser Cap represents the same LLLT technology used in the illumiflow 272 Laser Cap CSM-010. Given that LLLT devices for hair growth are designed to be utilized indefinitely, the illumiflow 148 Laser Cap is as safe and as effective over time as the predicate illumiflow 272 Laser Cap.

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[1] Mathematically calculated: There are 120 diodes in the LaserCap, operating at approximately 5mW per diode, making the power output calculation 120 diodes x 5mW = 600mW.

[2] Mathematically calculated: Verification test results in Section 14 of this 510k submission provide the following:
Laser Array Test: measure diode output: 5mW +/-10% [PASS]
Laser Cap Functional Test: laser power within the cap: 5mW +/-10% [PASS]
There are 148 diodes in the Laser Cap, operating at approximately 5mW per diode, making the power output calculation 148 diodes x 5mW = 740mW.

EGlobal, LLC asserts that the illumiflow 148 Laser Cap with its 148 diodes and 30-minute treatment session time is equivalent in form, function, safety, and efficacy to the current illumiflow 272 Laser Cap and the LaserCap 120; in addition, the LaserCap 120 predicate provides evidence of an FDA cleared device in the OAP product code with an energy dose similar in performance to the illumiflow 148 Laser Cap, both of which utilize fewer laser diodes than their predicates for the same intended use.