March 21, 2018

DermaScalp LLC
John Carullo
Managing Member
190 E. Stacy Rd
Suite 306-291
Allen, Texas 75002

Re: K173846
Trade/Device Name: DermaScalp Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 14, 2017
Received: December 19, 2017

Dear John Carullo:

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)*

K173846

Device Name

DermaScalp Laser Cap

Indications for Use *(Describe)*

The family of DermaScalp Laser Cap devices are indicated to treat Androgenetic Alpopecia and promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in Females who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-2, or frontal; both with Fitzpatrick Skin Types 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ATTACHMENT 2

510(k) SUMMARY

510(k) Owner:	DermaScalp LLC 190 E. Stacy Rd. Suite 306-291 Allen, TX 75002 Contact: John Carullo Phone: 214-683-0724
Date Summary Prepared:	December 14, 2017
Device:	Trade Name: DermaScalp Laser Caps
	Common/Classification Name: Light Therapy Hair System Product Code OAP 21 C.F.R. § 890.5500 (Infrared lamp)
	Classification: Class II
Predicate Devices:	iGrow II Hair Growth System - Apira Science Inc - K152019
	Capillus82, Capillus202, Capillus272 Pro, 272 OfficePro, Capillus302, Capillus312, and Capillus352 – Capillus LLC – K163170
	Transdermal LaserCap80, LaserCap120, LaserCap224, LaserCap300 – K161875
Reference Device:	DermaScalp Laser Cap - DermaScalp LLC - K152587 (Previously FDA cleared)

Device Description:	The family of DermaScalp Laser Cap devices are a hands-free, portable, non-invasive, low-level laser device intended to treat Androgenetic Alopecia (Hair Loss) and to promote hair growth in Males and Females. The DermaScalp Laser Cap devices provide distributed red laser light dispersing from a "Concave" scalp covering utilizing laser modules with a 650 nm wavelength, <5 mW output power, producing a continuous wave "CW" output beam. The "Concave" scalp covering is designed to maximize the delivery of the coherent laser light to effectively cover the entire scalp of the user during treatment.
Intended Use:	The family of DermaScalp Laser Cap devices are indicated to treat Androgenetic Alpopecia and promote hair growth in Males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in Females who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-2, or frontal; both with Fitzpatrick Skin Types I to IV.
Technological Characteristics:	The family of DermaScalp Laser Cap devices are a hands-free portable device that produce red laser energy dispersed from a "Concave" scalp covering as it rests upon a user's head and creates a laser field that covers the users entire scalp area. The devices produce timed treatments of equally distributed laser energy to the full scalp area. The treatment received from the laser energy promotes hair growth in both Males and Females and treats Androgenetic Alopecia (Hair Loss) by the therapeutic modality of bio-stimulation.
Biocompatibility Data:	The construction of the family of DermaScalp Laser Cap devices do not raise any biocompatibility issues. All the materials used in the construction of the DermaScalp devices were tested and adhere to the requirements of ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process, as well as, adhere to the requirements of ISO 10993-5:2009 Biological Evaluation of Medical Devices -- Part 5: Tests for in vitro cytotoxicity.
Performance Data:	The evaluation of the perfomance data presented confirms that the family of DermaScalp Laser Cap devices have the same or similar Laser Wavelength, Laser Power, Laser Energy Type, Output Mode, Treatment Time, Output Beam, Laser Field Treatment Area, Consumer Usage Focal Length as the FDA Cleared predicate devices. Testing to IEC 60601-1 and 60601-1-2 confirm the devices adherence to LVD electrical and EMC safetly requirements. Testing to IEC 60825-1 certifies the laser system to classifaction 3R, which is the same as the predicate devices. Testing to IEC 60601-1-11:2015 confirms the basic safety and essential

performance of medical electrical equipment and medical electrical systems for use in the home.

DermaScalp used a third party group to to administer a self-selection and usibility study to determine the user comprehension of user instructions, warnings, and precaustions. The testing was administered to 116 adult subjects of any age (>18) of diverse race, age, and educational background. The DermaScalp usibility test demonstrated a pass rate of 93% (self-selection) and 99.4% pass rate for the user instruction questionnaire, satisfying the FDA's requirements for clearance (sale) as Over-the-Counter Intended Use.

Performance Testing is conducted to confirm compliance to design specifications; all functions were verified to operate as designed. The DermaScalp devices met all acceptance criteria in the performance testing.

Substantial Equivalance: The family of DermaScalp Laser Cap devices referenced in this application are the same technology used by the LLLT devices cleared under device code OAP. The DermaScalp Laser Caps are as safe and effective as the predicate devices, as well as other reference devices in its class.

The sponsor believes that the difference in the physical appearance, number of diodes, or in the method of delivering the radiant energy of the systems is of no consequence and does not affect the therapeutic value or the safety profile. All compliant LLLT systems which use red light diode lasers are classified as class 3R laser systems according to the IEC standard for allowable emission levels, which is a recognized standard by the FDA as well, and the adverse event profile is the same.

DermaScalp Devices	**Capillus Devices**	**Transdermal Devices**	**iGrow**	**OAP Devices (General)**
To Be Determined	K163170	K161875	K152019	N/A
LLLT Device	LLLT Device	LLLT Device	LLLT Device	LLLT Device
OTC	OTC	Prescription	OTC	Prescription and OTC
Intended Use-Androgenetic Alopecia	Intended Use-Androgenetic Alopecia	Intended Use-Androgenetic Alopecia	Intended Use-Androgenetic Alopecia	Intended Use-Androgenetic Alopecia
Cap Design	Cap Design	Cap Design	Helmet Design	Helmet/Cap, Comb, Brush or Panel Design
650nm	650nm	650nm	655nm	635-678nm
Marketing Clearance for Males & Females	Marketing Clearance for Males & Females	Marketing Clearance for Males & Females	Marketing Clearance for Males & Females	Marketing Clearance for Males & Females
Passive Use (hands free)	Passive Use (hands free)	Passive Use (hands free)	Passive Use (hands free)	Passive Use (hands free or comb)

Diode Count- 50, 80, 120, 148, 180, 202, 224, 272	Diode Count- 82, 202, 272, 302, 312, 352	Diode Count- 80, 120, 224, 300	Diode Count- 51	Diode Count- Ranges from 1 to 352
Classification: OAP	Classification: OAP	Classification: OAP	Classification: OAP	Classification: OAP
Fitzpatrick Skin Phototypes – I-IV	Fitzpatrick Skin Phototypes – I-IV	Fitzpatrick Skin Phototypes – I-IV	Fitzpatrick Skin Phototypes – I-IV	Fitzpatrick Skin Phototypes – I-IV
Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females); Norwood Hamilton IIA-V (males); or both genders
Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment- approximately 17weeks, every other day (indefinite)
Total Laser Energy Output: <250mW, <400mW, <600mW, <740mW, <900mW, <1,010mW,<1,120mW, <1,360mW	Total Laser Energy Output: <410mW, <1,010mW, <1,360mW, <1,510mW, <1,560mW, and <1,760mW	Total Laser Energy Output: <400mW, <600mW, <1,120mW, <1,500mW	Total Laser Energy Output: <255mW	Total Laser Energy Output: Ranges from <5mW to <1,760mW
Device Class II	Device Class II	Device Class II	Device Class II	Device Class II

For these reasons, the family of DermaScalp Laser Caps satisfy the FDA's substantial equivalence requirements with respect to intended use, technological and design characteristics. With reference to all devices cleared through the OAP device classification, the sponsor respectfully proposes that the FDA has acknowledged that Low-Level Laser/Light Therapy is a viable modality for treating androgenic alopecia in both genders and that the red light lasers in class 3R, used in the DermaScalp devices referenced in this application are substantially equivalent to the predicates. Additionally, no new safety or efficacy concerns are raised due to the minor differences present between devices.

Conclusions: The family of DermaScalp Laser Cap devices are as safe and effective as the FDA Cleared predicate devices for male and female treatment, and is thefore Substantial Equivalent to the FDA Cleared predicate devices with respect to intended use, technological characteristics and safety characteristics.