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

February 4, 2016

Dermascalp LLC
Mr. John Carullo
Managing Member
1700 Alma Drive Suite 400
Plano, Texas 75075

Re: K152587
Trade/Device Name: DermaScalp Laser Cap
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: November 20, 2015
Received: January 4, 2016

Dear Mr. 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.

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 yours,

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)*
K152587

Device Name
DermaScalp Laser Cap
Models: DermaScalp MD Laser Cap & DermaScalp MDX Laser Cap

Indications for Use *(Describe)*
The DermaScalp Laser Cap is indicated to promote hair growth in females with Androgenetic Alpopecia who have Ludwig-Savin Classifications I-II and who have 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.

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Food and Drug Administration
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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 1700 Alma Dr. Suite 400 Plano, TX 75075 Contact: John Carullo Phone: 214-683-0724	
Date Summary Prepared:	Sebtember 04, 2015	
Device:	Trade Name:	DermaScalp Laser Cap
	Common/Classification Name:	Light Therapy Hair System Product Code OAP 21 C.F.R. § 890.5500 (Infrared lamp)
	Classification:	Class II
Predicate Devices:	LaserCap Elite - Transdermal Cap Inc - K150613 LaserCap PRO - Transdermal Cap Inc - K150613	
Device Description:	The DermaScalp MD Laser Cap and the DermaScalp MDX 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 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 DermaScalp Laser Cap is indicated to promote hair growth in females with Androgenetic Alpopecia who have Ludwig (Savin) Classifications I-II and who have Fitzpatrick Skin Types I to IV.
Technological Characteristics:	The DermaScalp MD Laser Cap and the DermaScalp MDX 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 Females and treats Androgenetic Alopecia (Hair Loss) by the therapeutic modality of bio-stimulation.
Biocompatibility Data:	The construction of the DermaScalp MD Laser Cap and the DermaScalp MDX Laser Cap devices do not raise any biocompatibility issues. All the materials used in the construction of the DermaScalp devices adhere to the requirements of ISO 10993-1:2009, Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process.
Performance Data:	The evaluation of the perfomance data presented confirms that the DermaScalp MD Laser Cap and the DermaScalp MDX 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. 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.
Conclusions:	The DermaScalp MD Laser Cap and the DermaScalp MDX Laser Cap devices are as safe and effective as the FDA Cleared predicate devices for female treatment and is thefore Substantial Equivalent to the FDA Cleared predicate devices with respect to intended use, technological characteristics and safety characteristics.

Substantial Equivalence Comparison Table

	New Device	Predicate Device
510(k) #	K152587	K150613
Company	DermaScalp LLC	Transdermal Inc
Name	DermaScalp MD Laser Cap	LaserCap Elite
Indications for Use	The DermaScalp MD Laser Cap is indicated to treat Androgenetic Alpopecia and to promote hair growth in Females who have Ludwig (Savin) I-II patterns of hair loss and who have a Fitzpatrick Skin Types I to IV.	LaserCap Elite is indicated to treat Androgenetic Alopecia and to promote hair growth in Females who have Ludwig (Savin) Hair Loss Classification of I to II, and who have a Fitzpatrick Skin Type of I to IV.
Indicated Use On	Females	Females
Cleared Use for	Prescription Use	Prescription Use
Device Type	Scalp Covering Device	Scalp Covering Device
Laser Assembly	Red Laser Diodes mounted within a "Concave" scalp covering	Red Laser Diodes mounted within a "Concave" scalp covering
Wavelength	650nm	650nm
Output Beam	Continous Wave "CW"	Continous Wave "CW"
Laser Diode Power (each)	<5mW Per IEC 60825-1 ED. 3.0 B:2014	<5mW Per IEC 60825-1 ED. 3.0 B:2014
Number of Laser Diodes/Optics	Eighty (80) for Females	Eighty (80) for Females
Total Laser Energy Output	<400mW for Female use	<400mW for Female use
Light Energy Type	Coherent Laser	Coherent Laser
Laser Field	Entire Scalp Area	Entire Scalp Area
Laser Diode Array	Linear Rows within a "Concave" scalp covering	Linear Rows within a "Concave" scalp covering
Total Treatment Time	30 minutes	30 minutes
Device Application	Portable	Portable
Consumer Usage Focal Length	0.5" – 1.5" from Emanating Diode Location	0.5' – 1.5" from Emanating Diode Location
Ambient Operating Temperature	50° to 86°F (10° to 30°C)	32° to 104°F (0° to 40°C)
Safety	CE Mark	CE Mark
User Manual	Yes	Yes

Substantial Equivalence Comparison Table

	New Device	Predicate Device
510(k) #	K152587	K150613
Company	DermaScalp LLC	Transdermal Inc
Name	DermaScalp MDX Laser Cap	LaserCap PRO
Indications for Use	The DermaScalp MDX Laser Cap is indicated to treat Androgenetic Alpopecia and promote hair growth in Females who have Ludwig (Savin) Hair Loss Classification of I-II patterns of hair loss and Fitzpatrick Skin Types I to IV.	LaserCap PRO is indicated to treat Androgenetic Alopecia and promote hair growth in Females who have Ludwig (Savin) Hair Loss Classification of I to II, and who have been determined to have a Fitzpatrick Skin Type of I to IV.
Indicated Use On	Females	Females
Cleared Use for	Prescription Use	Prescription Use
Device Type	Scalp Covering Device	Scalp Covering Device
Laser Assembly	Red Laser Diodes mounted within a "Concave" scalp covering	Red Laser Diodes mounted within a "Concave" scalp covering
Wavelength	650nm	650nm
Output Beam	Continous Wave "CW"	Continous Wave "CW"
Laser Diode Power (each)	<5mW Per IEC 60825-1 ED. 3.0 B:2014	<5mW Per IEC 60825-1 ED. 3.0 B:2014
Number of Laser Diodes/Optics	Two hundred twenty-four (224) for Females	Two hundred twenty-four (224) for Females
Total Laser Energy Output	<1,120mW for Female use	<1,120mW for Female use
Light Energy Type	Coherent Laser	Coherent Laser
Laser Field	Entire Scalp Area	Entire Scalp Area
Laser Diode Array	Linear Rows within a "Concave" scalp covering	Linear Rows within a "Concave" scalp covering
Total Treatment Time	30 minutes	30 minutes
Device Application	Portable	Portable
Consumer Usage Focal Length	0.5" – 1.5" from Emanating Diode Location	0.5' – 1.5" from Emanating Diode Location
Ambient Operating Temperature	50° to 86°F (10° to 30°C)	32° to 104°F (0° to 40°C)
Safety	CE Mark	CE Mark
User Manual	Yes	Yes