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

September 30, 2016

Transdermal Cap, Inc.
Michael Rabin
CEO
938 Chestnut Run
Gates Mills, Ohio 44040

Re: K161875
Trade/Device Name: Lasercap300, Lasercap224, Lasercap120, Lasercap80
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: July 6, 2016
Received: July 8, 2016

Dear Michael Rabin:

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 Part 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 Parts 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,

Christopher J. Ronk -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)*
K161875

Device Name
LaserCap300, LaserCap224, LaserCap120, LaserCap80

Indications for Use *(Describe)*
LaserCap300, LaserCap224, LaserCap120, and LaserCap80 are intended for the promotion of hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of 1 - 11 and males with androgenetic alopecia who have Hamilton-Norwood Classifications of lla-V and for both, 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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510 (k) Summary K161875

Transdermal Cap, Inc.

Submitter and Sponsor Contact Information	
Name:	Michael Rabin, MD, CEO
Address:	Transdermal Cap, Inc. 938 Chestnut Run Gates Mills, OH 44040 440-241-1846 860-201-1846F
Name of Devices	
Trade Names	LaserCap300, LaserCap224, LaserCap120, LaserCap80
Common or Usual Name	Lamp, non-heating, for promotion of hair growth
Classification Name	Infrared lamp per 21 CFR 890.5500
Classification Code	OAP (Laser, comb, hair)
Predicate Devices	
Device Trade Name	Manufacturer
Capillus272 (K160285, K143199) Capillus 202 (K160285, K153618) Capillus 82 (K160285, K151516)	Capillus, LLC
Reference Devices	
Lasercomb82 (K142573)	Lexington International
Lasercomb41 (K142573)	
Date Prepared	July 6, 2016

Intended Use / Indications for Use

LaserCap300, LaserCap224, LaserCap120, and LaserCap80 are indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I- II, males with androgenetic alopecia who have Hamilton-Norwood classifications Ila-Vand for both genders, Fitzpatrick Classification of Skin Phototypes I to IV.

Technological Characteristics

LaserCap300, LaserCap224, LaserCap120, and LaserCap80 consist of red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner, and configured for portable use with rechargeable battery and adapter. The devices only vary in number of lasers (300, 224, 120, and 80 diodes, respectively) and LaserCap300 has a small extension of the LaserCap housing perimeter where its additional laser diodes target peripheral hair-bearing areas of the scalp. As stated in prior submissions, the devices emit an audible tone at the beginning and end of a therapy session, indicating that therapy has begun (1 short beep) or ended (one long beep). The portable systems are powered by rechargeable Li-Ion battery cells assembled into a proprietary battery pack. Both the battery pack and charger are fully compliant to recognized, international standards.

Performance Data

Performance testing was conducted to confirm compliance to design specifications; all functions have been verified to operate as designed. All acceptance criteria were met by the device. The LaserCap300, LaserCap224, LaserCap120, and LaserCap80 conform to the standard IEC-60825-2007-03. This IEC standard is a recognized and accepted standard by the FDA. The guidance document for this accepted standard is found in the Federal register, July 26, 2001 (volume 66, Number 144). This report validates the LaserCap300, LaserCap224, LaserCap120, and LaserCap80 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliwatts maximum. With regard to all LaserCap models and predicate devices, there are no reported adverse events for this technology.

Non-clinical Testing

The LaserCap family of devices were tested for standards conformance with IEC 60825-1, IEC 60601-1-11, IEC 60601- 1-2, and IEC 62133. The materials used in LaserCap construction that come in contact with the skin are the same biocompatible materials as the predicates.

Substantial Equivalence

The LaserCap family of devices referenced in this application are the same technology used by the other Low Level Laser Therapy (LLLT) devices cleared under device code OAP. The LaserCap300, LaserCap224, LaserCap120, and LaserCap80 are as safe and effective as the predicate devices. The sponsor is certain that the difference in number of diodes is of no consequence and does not affect safety or efficacy as there are a wide range of number of diodes in the predicate devices listed and in other LLLT devices cleared under device code OAP. 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.

	LaserCap Devices	Predicates
Device Trade Name	LaserCap300, LaserCap224, LaserCap120, LaserCap80 *	Capillus272, Capillus202, Capillus82 (K160285)
Device Type	LLLT	LLLT
Prescription	Yes	yes
Intended Use	Androgenetic Alopecia	Androgenetic Alopecia
Design	Helmet/Cap	Helmet/Cap
Laser Diode Power	<5mW	<5mW
Laser Diode Class	3R	3R
Wavelength	650nm	650nm
User Gender	Women; Men pending clearance	Women and Men
Passive Hands-free use	Yes	yes
Number of diodes	80, 120, 224, 300	82, 202, 272
Classification	OAP	OAP
Common Usage Name	Lamp, Non-heating	Lamp, Non-heating
Fitzpatrick Skin Phototypes	I-IV	I-IV
Ludwig-Savin Scale (women)	I-II	I-II
Norwood-Hamilton (men)	IIa-V (pending clearance)	Iia-V
Treatment Frequency	17 weeks, every other day (indefinite)	17 weeks, every other day (indefinite)
Device Class	II	II

* LaserCap224 and LaserCap80 are legally marketed devices under the names LCPRO with 224 laser diodes and LCELITE with 80 laser diodes, respectively; K150613. Names changed in this submission for naming consistency with the proposed expanded family of LaserCap devices.

Based on technology, therapy outcome, similar design, wavelength choice, and treatment session time (all substantially equivalent), the expansion of the use for males from one device to

its equivalent is reasonable and consistent with the known uses attributed to LLLT devices in general, and over a wide range in number of laser diodes, between devices. The predicate Capillus family of devices has been cleared for use in both men and women and there have been no reported safety issues with any LLLT device to date, with many indicated for use in both men and women. It is therefore established that there is no difference between the devices, the regimens, or the technology; and the number of diodes does not adversely affect the safety of the devices. Thus, the sponsor maintains that the indications for use for the submitted LaserCap devices should apply as stated: The LaserCap300, LaserCap224, LaserCap120, and LaserCap80 are 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. For these reasons, the LaserCap300, LaserCap224, LaserCap120, and LaserCap80 satisfy the FDA's substantial equivalence 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 androgenetic alopecia in both genders and that the red light lasers in class 3R, used in the LaserCap 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.

In summary, the LaserCap family of legally marketed devices and proposed new devices are essentially identical to the Capillus family of legally marketed devices, except for some small variations in number of laser diodes in the devices. And varying the number of laser diodes in these devices should not change safety or efficacy of these devices, as evidenced by predicate devices Capillus82 and Capillus202 which were new devices cleared by Special 510 (k) K151516 and K153618, respectively, using a 272 diode laser cap device as the predicate, and by reference devices Hairmax Lasercomb41 and Lasercomb82 for use in men and women (K142573) which were cleared using a 9 laser diode lasercomb as the predicate device.