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

Transdermal Cap Incorporated
% Mr. Raymond R. Blanche
NST Consulting, LLC
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

July 22, 2015

Re: K150613
Trade/Device Name: LaserCap LCPro and LCElite
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: June 17, 2015
Received: June 19, 2015

Dear Mr. Blanche:

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" (21CFR 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,

Joshua C. Nipper -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)*
K150613

Device Name
LaserCap LCPro and LCElite

Indications for Use *(Describe)*
The LC PRO and LC ELITE are indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I-II and Fitzpatrick Classification of skin phototypes of I-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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510(k) Summary

Transdermal Cap, Inc.

Submitter's Contact Information

Name: Raymond R. Blanche

Address: NST Consulting, LLC
641 Shunpike Road, Suite 311
Chatham, NJ 07928

Telephone: (973) 539-7444
Facsimile: (973) 539-7445

Name of Device and Name/Address of Sponsor

Trade Name: Lasercap, LCPro and LCElite

Sponsor Contact Information: Michael Rabin, MD
Transdermal Cap, Inc.
3615 Superior Avenue, Suite 3104F
Cleveland, Ohio 44114
T. 877-711-4769
F. 860-201-1846

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 Pro – K143199	Capillus, LLC
Theradome LH 80 Pro – K113097	Theradome, Inc.

Reference Devices:

Hairmax Lasercomb - K142573	Lexington International

Date Prepared: July 16, 2015 Revised

Intended Use / Indications for Use

The LCPro and LCElite are indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I - II and Fitzpatrick Classification of Skin Phototypes I to IV.

Technological Characteristics

The LCPro consists of 224 red, visible-light, pulsed-emission diode lasers operating at 650 nanometers, that are configured within a protective inner liner and outer helmet. The LCElite is physically similar to the LCPro, except that it is configured with 80 red, visible-light, continuous-emission diode lasers, also operating at 650 nanometers and also configured within a protective inner liner and outer helmet. The use of these specific number of diode lasers provides for a full coverage of the upper 1/3 of the head; i.e., the area commonly covered with stylized hair. The helmet system will automatically pause therapy if the subject's head is moved outside of the zone of radiation and will resume therapy when the correct head position is re-established. This is achieved by a safety interlock. At the beginning and end of a therapy session, audible tones are delivered to the user, indicating that therapy has begun (2 beeps) or ended (one long beep). The system is powered by rechargeable Lithium Ion battery cells assembled into a proprietary battery pack. Both the battery cells pack and charger are fully compliant to recognized, international standards.

Performance Data:

No Clinical trial data for LCPro and LCElite were submitted for this 510(k). The LCPro and LCElite were tested for standards conformance with IEC 60825-1, IEC 60601-1-11, IEC 60601-1-2, and IEC 62133.

Substantial Equivalence

The LCPro and LCElite utilize the same technological characteristics as the predicate devices. The LCPro uses the same pulsing characteristics for its laser diodes as the K143199 (Capillus272 Pro) device, and provides similar energy and irradiance output to the treatment area as this predicate. The LCElite uses continuous-output laser diodes as the K113097 (Theradome LH80 Pro) device does, and provides similar energy and irradiance output to the treatment area as this predicate The LCPro contains 224 lasers and the LCElite contains 80. The target audience of these devices is the same. The two offerings are presented to offer the prescribing physician an economic alternative for his patients.

The LCPro and LCElite are designed to provide low-level-laser therapy. Both predicate devices and the proposed devices use red light diode lasers. The sponsor believes that the differences between the subject devices of this 510(k) compared with the predicate devices, do not substantially affect the therapeutic value or the safety profile. There are differences in the physical appearances of the LCPro and LCElite, compared to the predicates.

Conclusion

The LCPro and LCElite utilize the same technological characteristics as the predicate devices listed above, and are to be used for the same intended use. The sponsor believes that there are no new types of safety and effectiveness questions for the LCPro and LCElite when compared with

the predicate devices, and therefore that the devices should be considered substantially equivalent to the predicate devices.