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

January 29, 2015

Capillus, LLC
% Mr. Raymond Blanche
NST Consulting, LLC
641 Shunpike Road, Suite 311
Chatham, New Jersey 07928

Re: K143199
Trade/Device Name: Capillus 272 Pro
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 17, 2014
Received: December 29, 2014

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,

Jennifer R. Stevenson -A

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)*
K143199

Device Name
Capillus 272
Pro

Indications for Use *(Describe)*
The Capillus272 Pro is 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.

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

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510(k) Summary
K143199
Capillus, LLC

Date Prepared: **October 24, 2014**

Submitter's Contact Information:

Name: Patricia Schnoor

Address: Capillus LLC
1430 S. Dixie Hwy.
Coral Gables, FL 33146

Telephone: (786) 888-1874
Facsimile: (305) 418-7581

Name of Device and Name / Address of Sponsor:

Trade Name: Capillus272 Pro

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)

Sponsor Contact Information: Frances Pina-Brea
Capillus LLC
1430 S. Dixie Hwy.
Coral Gables, FL 33146

Telephone: (786) 888-1871

Predicate Devices:

Device Trade Name	Manufacturer
iGrow II Hair Growth System	Apira Science, Inc.
MEP-90	Midwest, RF, LLC
Theradome LH80Pro	Theradome, Inc.

Reference Devices:

Device Trade Name	Manufacturer
Hairmax Lasercomb	Lexington International

Intended Use / Indications for Use:

The Capillus272 Pro is indicated to promote hair growth in adults with androgenic alopecia who have Ludwig-Savin Classifications of I- II and Fitzpatrick Classification of Skin Phototypes I to IV.

Technological Characteristics

The Capillus272Pro consists of 272 red, visible light, diode lasers operating at 650 nanometers, configured within an outer helmet and protective inner liner. The use of this 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 Nickel Metal Hydride battery cells assembled into a proprietary battery pack. Both the battery cells, pack and charger are fully compliant to recognized, international standards.

Performance Data:

A multi-center, randomized, double blinded, placebo controlled, prospective trial was conducted at two sites in the United States. Subjects received either the Capillus272 Pro (called theHandi-Dome Laser for the trial), unlabeled with any markings or an equivalent, red light, incandescent light system. Identical, helmet housings were used for both light sources to further maskthe actual test device from the placebo device. Adequate data, from prior testing, was already available to the sponsor, validating the efficacy of the Capillus272 Pro, obviating the need to test lasers versus LEDs, which the sponsor and the FDA consider equal in their tissue interaction profile. All subjects self-administered treatments, at home, for 17 weeks, with either the actual test device or the placebo device. Treatments were administered every other day, for 30minutes. Subjects treated in the actual test laser group demonstrated a 100 % effectiveness; that is, all of the subjects showed a positive result for an increase in terminal hair counts. In the placebo group, there was some incremental improvement over baseline and some demonstrated a decrease over baseline. Overall, the active group demonstrated a 51% positive variance over the placebo group from baseline. Most significant was the actual test group's decrease in terminal hair counts which was zero compared to the placebo group which was highly significant. This points strongly to the hypothesis that red laser light's characteristics for delivering precise, controlled, consistent irradiance is essential in effecting a reproducible therapeutic outcome.

There were no anticipated adverse events and none were reported from either therapy administered that were study related. In all instances the Capillus272 Pro functioned as anticipated and hair re-growth was observed to be significantly greater than that of the incandescent placebo system

Substantial Equivalence

The Capillus272Pro is the same technology used by all predicates and reference devices. This is Low Level laser/Light Therapy. The Capillus272 Pro is as safe and effective as the predicate devices, the iGrow, Mep-90 and Theradome and the other reference device in its class, the Hairmax Lasercomb. The Food and Drug Admi1listration has created a new classification for this device, effective January 18, 2007. It is called OAP. There are no other devices listed within this classification, which the sponsor believes serves to narrow down the predicate device issue to one key comparison. Does theCapillus272 Pro demonstrate substantial equivalence to the iGrow II Hair Growth System, the MEP-90 and the Theradome LH80Pro for females indicated use and to for the specific design characteristic of helmet or cap? The sponsor believes that with the exception of the configuration of the optical elements, the predicate devices are the same devices in form, function safety and efficacy as the Capillus272 Pro. The Hairmax Lasercomb is offered as a reference proof of the functionality and acceptability of the first device to be cleared by the FDA in the category of OAP, both technically and clinically.

All systems, which use red light diode lasers and/or the equivalent, super-luminescent, light

emitting diodes, are classified as class 3B laser systems by 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. The sponsor believes that the difference in the physical appearance 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. The sponsor believes that differences between systems does not create a performance difference, but rather a physical appearance difference only. Finally, the clinical data summarized in the 510(k) notice confirms the safety and efficacy of the Capillus272 Pro for prescription use, according to Part 21 CFR 801 Subpart D. For these reasons, the Capillus272 Pro satisfies the FDA's substantial equivalence with respect to intended use, technological and design characteristics.

With the relatively new classification of OAP, the sponsor respectfully proposes that the FDA has acknowledged that Low-Level Laser/Light Therapy is a viable modality for treating androgenic alopecia in the specified patient group and that the red light lasers in class 3B, used in theCapillus272 Pro as well as the predicate devices, are substantially equivalent to the predicates.

The clinical data presented by the sponsor for the Capillus272 Pro further validates that red light lasers are effective in promoting hair growth and does not present any safety issues. Therefore, the Capillus272 Pro satisfied the FDA's substantial equivalence criteria. Thus, the FDA should clear the device via the 51O(k) notice containing clinical data.