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

June 9, 2015

Capillus, LLC
Ms. Patricia Schnoor
Quality Manager
1430 South Dixie Highway, Suite 304
Coral Gables, Florida 33146

Re: K150578
Trade/Device Name: Capillus272 OfficePro
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: March 24, 2015
Received: March 25, 2015

Dear Ms. Schnoor:

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 -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)*
K150578

Device Name
Capillus272 OfficePro

Indications for Use *(Describe)*
Promote hair growth in females diagnosed with androgenetic alopecia presenting with Ludwig-Savin Classifications I-II and Fitzpatrick Skin Phototypes 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Capillus, LLC

Date Prepared: **June 2, 2015**

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 OfficePro

Common or Usual Name: Low level laser for promotion of hair growth

Classification Name: LLLT per 21 CFR 878.4810

Classification Code: OAP (Laser, Comb, Hair)

Sponsor Contact Information: Patricia Schnoor
Capillus LLC
1430 S. Dixie Hwy.
Coral Gables, FL 33146

Telephone: (786) 888-1874

Predicate Devices:

Device Trade Name	Manufacturer
iGrow II Hair Growth System	Apira Science, Inc.
Sunetics Clinical Laser "G" or "W2326"	Sunetics international Marketing Group LLC
Capillus 272 Pro	Capillus, LLC

Reference Devices:

Device Trade Name	Manufacturer
Hairmax Lasercomb	Lexington International

Intended Use / Indications for Use:

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

The Capillus272 OfficePro is intended for use in a dry, indoor environment.

Technological Characteristics

The Capillus272 OfficePro is exactly the same as the Capillus272 Pro in every way **except** the following:

1. The Capillus272 OfficePro is the same hat, but mounted on a stand. The same electrical design has been applied (i.e. adapter steps down to ~12V DC; but no battery as it is not intended to be portable).

The Capillus272 Pro consists of 272 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 Capillus272 OfficePro is intended for in-office use and is not intended to be portable. The same hat is mounted on a stand and the adapter is connected directly to the cap through wiring threaded through the stand.

Just as for the previous version, 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 (Capillus272 Pro only) 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 criterion were met by the device. See Section 12 for standards met and test reports.

The performance data included (Section 12) demonstrates that the Capillus272 Pro has the same or similar laser wavelength, output power, output beam, energy type, laser field, treatment area, and energy delivered (J/cm^2) as the declared predicates. Just as for all predicates (K143199) and reference devices (K140931, K141567, K132646), there are no reported adverse events for this technology.

Substantial Equivalence

The Capillus272 OfficePro is the same technology used by Capillus272 Pro (K143199) and all reference devices. The Capillus272 OfficePro is as safe and effective as the Capillus272 Pro, the iGrow, and Sunetics as well as other reference devices in its class, such as the Hairmax Lasercomb.

One key question remains - does the Capillus272 OfficePro demonstrate substantial equivalence to the other devices in its class? 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 OfficePro. The Hairmax Lasercomb, offered as a reference, is 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. 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 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.

For these reasons, the Capillus272 OfficePro satisfies the FDA's substantial equivalence requirements with respect to intended use, and technological and design characteristics.

With the 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 both genders and that the red light lasers in class 3R, used in the Capillus272 Pro and Capillus272 OfficePro, are substantially equivalent to the predicates. Additionally, no new safety or efficacy concerns are raised due to the minor differences present between devices.