DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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January 31, 2017

Capillus, LLC
Patricia Schnoor
Director, Quality & Regulatory Affairs
1715 NW 82nd Avenue
Miami, Florida 33126

Re: K163170
Trade/Device Name: Capillus 82, Capillus 202, Capillus 272 Pro, 272 Office Pro, Capillus 302, Capillus 312, and Capillus 352
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: November 4, 2016
Received: November 14, 2016

Dear Patricia 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" (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,

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)*

K163170

Device Name
Capillus Laser Domes: Capillus82, Capillus202, Capillus272 Pro, Capillus272 Office Pro, Capillus302, Capillus312, and Capillus352

Indications for Use *(Describe)*
The Capillus laser domes 82, 202, 272 Pro, 272 OfficePro, 302, 312, and 352, are intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-2, or frontal; both with 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.

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

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510(k) Summary

Capillus, LLC

Date Prepared: **November 04, 2016**

Submitter's Contact Information:

Name: Patricia Schnoor

Address: Capillus LLC
1715 NW 202nd Avenue
Miami, FL 33126

Establishment Registration# 3010123655

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

Name of Device and Name / Address of Sponsor:

Trade Name: Capillus82, Capillus202, Capillus272 Pro, 272 OfficePro, Capillus302, Capillus312, and Capillus352

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:
Patricia Schnoor
Capillus LLC
1715 NW 82nd Avenue
Miami, FL 33126

Telephone: (786) 888-1874

Predicate Devices:

Device Trade Name	Manufacturer	510(k)
Hairmax Lasercomb	Lexington International	103368, 142573
iGrow II	Apira	141567

Intended Use / Indications for Use:

The Capillus laser domes 82, 202, 272 Pro, 272 OfficePro, 302, 312, and 352, are intended to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa to V patterns of hair loss and to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) Scale I-1 to I-4, II-1, II-2, or frontal; both with Fitzpatrick Skin Types I to IV.

Technological Characteristics

The Capillus272 Pro and Capillus272 OfficePro both consist 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 (Capillus272 Pro) and salon/spa use (Capillus272 OfficePro). The Capillus82, Capillus202, Capillus302, Capillus312, and Capillus352 are exactly the same as the Capillus272 Pro with the exception of the number of diodes which are respective of model (e.g. 82 diodes in Capillus82).

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 (2 short beeps) 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. The OfficePro is directly powered by the DC charger, which is 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 devices. The Capillus82, Capillus202, Capillus272 Pro, 272 OfficePro, Capillus302, Capillus312, and Capillus352 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) [page 39049 39050]. This report validates for the Capillus82, Capillus202, Capillus272 Pro, 272 OfficePro, Capillus302, Capillus312, and Capillus352 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 61959.

The data presented in this submission is restricted to self-selection and usability to include comprehension of user instructions, warnings, and precautions. The results of a pre•submission request (Q160385) verified the objectives that must be fulfilled for the Capillus family of devices to be classified for over-the-counter (OTC) sale. One of the responses for the Q-submission indicated that a minimum of an 80% success rate must be achieved for the intended use of OTC to be granted. The testing was administered to **55 adult subjects of any age (>18)**, educational background, race, disease status present or pre-education about the testing to be performed. This was designed to provide for the broadest test criteria without any bias being imposed, thereby assessing the real-world capability of the average adult, "retail customer" who might wish to purchase a device without the benefit of a physician or other qualified health care provider to provide counsel as is the case with prescription devices. The study was conducted in two (2) parts specifically intended to demonstrate that the device is appropriate for consumer use by lay persons (see data and report in Section 13). The first part addressed self-selection (box labeling), while the second part addressed the content of the user manual including warnings and precautions. The Capillus usability test demonstrated a pass rate of **94.6%** (self-selection) and **90.9%** pass rate for user instruction questionnaire, satisfying the FDA's requirements for clearance (sale) as Over-the-Counter Intended Use.

Just as for Capillus272 Pro (K143199) and reference devices, there are no reported adverse events for this technology.

Substantial Equivalence

The requirements set for substantial equivalence in the traditional sense, do not have applicability in this process as the purpose of this submission is expansion of indications for use to include OTC sale capability. However, The Hairmax Lasercomb and iGrow Hair Growth System (predicate devices) have been cleared with the Intended Use of Over-the-Counter, and the Capillus devices can demonstrate the minimum pass-rate for usability by lay persons. The Capillus devices utilize the same technology and share the same risk profile as the predicates. The Capillus family of devices referenced in this application are the same technology used by all LLLT devices cleared under device code OAP. The Capillus272 Pro, Capillus272 OfficePro, Capillus82, Capillus202, Capillus302, Capillus312 and Capillus352 are as safe and effective as the predicate devices, as well as other reference devices in its class.

Capillus Devices	**iGrow**	OAP (General)
K143199; K150578; K151516; K153618	K122248; K140931	N/A
LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use	Prescription and OTC
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use -Androgenic Alopecia
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R and LEDs	Contain Laser Diodes- Class 3R; LEDs, or a combination of both
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap, comb, or flat Design
650nm	650nm	650nm
Marketing clearance for Females	Marketing clearance for Males and Females	Marketing clearance for both genders
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands-Free, or comb
272 Laser Diodes	21 Laser Diodes; 30 LEDs	Various configurations of lasers, LEDs or both
OAP Classification	OAP Classification	OAP Classification
Classification Name -Infrared Lamp	Classification Name -Infrared Lamp	Classification Name - Infrared Lamp
Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non-Heating	Common Usage Name - Lamp, Non- Heating
General & Plastic Surgery Committee	General & Plastic Surgery Committee	General & Plastic Surgery Committee
Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I- IV	Fitzpatrick Skin Phototypes - I -IV
Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females) Norwood Hamilton IIA-V (males)	Ludwig-Savin I-II (females); Norwood Hamilton IIA-V (males); or both
Efficacy Rates - High Compared to Placebo	Efficacy Rates – 34-41%	Various; trial results are all significant increase with respect to placebo.
Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment - ~16 weeks, every other day (indefinite)
Device Class II	Device Class II	Device Class II

For these reasons, the Capillus family of laser domes satisfy the FDA's substantial equivalence requirements with respect to risk profile, intended use, and technological and design characteristics. Additionally, no new safety or efficacy concerns are raised due to the minor differences present between devices.