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

April 25, 2016

Capillus, LLC
Ms. Patricia Schnoor
Director, Quality, Safety, & Compliance Manager
1715 NW 82nd Ave
Miami, Florida 33126

Re: K160285
Trade/Device Name: Capillus272 Pro, Capillus272 Officepro, Capillus82, Capillus202
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: February 1, 2016
Received: February 3, 2016

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" (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 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)*
K160285

Device Name
Capillus272 Pro, Capillus272 OfficePro, Capillus82, Capillus202

Indications for Use *(Describe)*
The Capillus272 Pro, Capillus272 OfficePro, Capillus82, and Capillus202 are intended for the promotion of hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I- II, and in males with androgenic alopecia who have Norwood Hamilton Classifications IIa-V ; and both genders having Fitzpatrick Classification of 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.

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510(k) Summary

Capillus, LLC

Date Prepared: **February 01, 2016**

Submitter's Contact Information:

Name: Patricia Schnoor

Address: Capillus LLC
1715 NW 82nd 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: Capillus272 Pro, Capillus272 OfficePro, Capillus82, Capillus202

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)
iGrow II	Apira	122248, 140931
HairMax LaserBand	Lexington International	142573

Reference Devices:

Device Trade Name	Manufacturer
Hairmax LaserComb	Lexington International

Intended Use / Indications for Use:

Capillus272 Pro, Capillus272 OfficePro, Capillus82, and Capillus202 are intended for the promotion of hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I – II, and in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa-V; and both genders having Fitzpatrick Classification of Skin Phototypes I-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 clinical office use (Capillus272 OfficePro). The Capillus82 and Capillus202 are exactly the same as the Capillus272 Pro with the exception of the number of diodes which are 82 and 202 respectively.

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 device. The Capillus272 Pro, Capillus272 OfficePro, Capillus82, and Capillus202 conform to the standard IEC-602825-2007-03. 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 Capillus272 Pro, Capillus272 OfficePro, Capillus82, and Capillus202 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 60950.

With regard to all Capillus models and reference devices, there are no reported adverse events for this technology.

Substantial Equivalence

The Capillus family of devices referenced in this application are the same technology used by the other LLLT devices cleared under device code OAP. The Capillus272 Pro, Capillus272 OfficePro, Capillus82 and Capillus202 are as safe and effective as the predicate devices, iGrow and HairMax LaserBand, as well as other reference devices in its class, such as the Hairmax LaserComb. 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.

Capillus is certain 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 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.

Capillus Devices	**iGrow**	HairMax LaserBand
K143199; K150578; K151516; K153618	K122248; K140931	K142573
LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use	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
Helmet/Cap Design	Helmet/Cap Design	Hair band, move over scalp
650nm	650nm	655nm
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 + user placement
272 Laser Diodes	21 Laser Diodes; 30 LEDs	82 (3 positions) = 246 laser diodes
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)	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%	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

Based on technology, therapy outcome, similar design, wavelength choice, and treatment session time (all substantially equivalent), the expansion of the use for males (as indicated in the iGrow) from one device to its equivalent is reasonable and consistent with the known uses attributed to LLLT devices in general. The iGrow device demonstrated equivalence between genders with 21 diodes and HairMax proved the non-gender-bias concept with the equivalent of 246 diodes. There have been no reported safety issues with any LLLT device to date. 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, Capillus claims the indications for use (all Capillus devices) should apply as stated: *The Capillus272 Pro, Capillus272 OfficePro, Capillus82, and Capillus202 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 Capillus272 Pro, Capillus272 OfficePro, Capillus82, and Capillus202 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 androgenic alopecia in both

genders and that the red light lasers in class 3R, used in the Capillus 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.