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 19, 2016

Capillus LLC
Ms. Patricia Schnoor
Manager, Quality & Regulatory Affairs
1715 Northwest 82nd Avenue
Miami, Florida 33126

Re: K153618
Trade/Device Name: Capillus202
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: December 16, 2015
Received: December 18, 2015

Dear 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 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)*
K153618

Device Name
Capillus202

Indications for Use *(Describe)*
The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and with 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.

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Special 510(k) Summary

Capillus, LLC

Date Revised: **January 13, 2016**

Submitter's Contact Information:

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

Estab't Reg#: 3010123655

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

Name of Device and Name / Address of Sponsor:

Trade Name: 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)
Capillus272 Pro	Capillus LLC	143199
LaserCap LCPro	Transdermal Cap, Inc	150613

Reference Devices:

Device Trade Name	Manufacturer
Hairmax Lasercomb	Lexington International

Intended Use / Indications for Use:

The Capillus202 is indicated to promote hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications of I-II, and with Fitzpatrick Skin Phototypes I-IV.

Technological Characteristics

The Capillus202 is exactly the same as the Capillus272 Pro in every way **except** the following:

1. **The Capillus202 has fewer diodes – 202 compared to 272 for Capillus272 Pro**

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 Capillus202 consists of 202 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.

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 assembled into a proprietary battery pack. Both the battery pack and charger are fully compliant to recognized, international standards.

Design Control Activities:

The Capillus design and development team followed ANSI/AAMI/ISO 14971:2007/(R)2010 Risk Management: Medical devices – Application of risk management to medical devices. Significant changes included assessing the effect a reduction of lasers would have on the end product, both for safety and for efficacy. All residual risks are found acceptable and the risk management file and summary are available for review. Based on the Capillus272 Pro, the verification and validation activities remain the same (e.g. output of each laser, operation of safety interface, and output of power pack), and were performed and assessed by designated personnel qualified to perform such activities. All methods, tests, and acceptance criteria are stipulated on the verification and validation reports. All documents are available for review.

Safety ratings remained the same; there was no change to the output of the individual lasers ($\leq$ 5mW); however, the "dose" (total delivered energy/cm2) is reduced due to reduced number of lasers. This may affect efficacy; this observation is made based on the performance of other devices similar to Capillus that are currently cleared under device code OAP and utilize much fewer than 272 lasers (The closest equivalent in light sources is Transdermal with a total of 224 lasers).

Use instructions do not change. Indications for use and the dose schedule remain exactly the same as for Capillus272 Pro and as for other devices in the same category (product code OAP); which is for maximum 30 minutes, every other day.

The output of the laser diodes was verified to remain the same (each diode) as for the previous model. Design control activities were followed per 21 CFR 820.30:

a) **General: The Capillus LLC Quality Management System is compliant to the requirement of the quality system regulation and specifically to design controls as stipulated by 21 CFR 820.30.**

b) **Design and development planning:** During project planning activities, the risks were identified and assessed with respect to the proposed design change. The proposed design change was minimal and affected only the number of diodes in the PCB array. The power pack remains exactly the same. Review of the risk assessment from previous model revealed no significant changes or risks are identified for the new model Capillus202. Vigilance activities for the Capillus272 Pro indicated that there were no significant problems identified (no adverse events reported).

c) **Design input:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project.

d) **Design output:** Design requirements for the Capillus272 Pro are transferred to the Capillus202 and an input/output matrix completed as for the original project. Design outputs are verified per performance tests.

e) **Design review:** Appropriate design reviews were conducted; in this case (due to minimal change), a technical evaluation, and a verification of inputs and outputs (physical values) were completed.

f) **Design verification:** All verification activities to assess the impact of the change (reduction of number of laser diodes) were completed. Laser diode output remains the same, but total dosage is reduced. Since the cap is intended to be used indefinitely (if treatment is stopped, results are lost – see instructions for use), this will likely affect only the time required to witness the same result as achieved with the Capillus272 Pro. The Capillus202 is offered as a lower-cost alternative.

g) **Design validation:** Feedback from hair restoration specialists and consumers indicate that a lower-cost alternative is desired. The slower efficacy is accepted, with the understanding that treatment is intended to be indefinite.

h) **Design transfer:** The Capillus family of products are manufactured on-site in the factory in Miami. Design transfer was minimal; training requirement to the new PCB was minimal, and all other components (including overall build) remained the same.

i) **Design changes:** The design of all models follows our established design control, change control, document control procedures.

j) **Design history:** The design history file for the Capillus202 is available for review.

Performance Data:

All verification and validation activities were performed by designated individuals. The results (available for review) demonstrate that the predetermined acceptance criteria were met.

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 Capillus202 conforms to the standard IEC-602025-2007-03; 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 Capillus202 the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 61959.

The performance data available for review demonstrates that the Capillus202 has exactly the same laser wavelength, output power (per diode), output beam, energy type, laser field, and treatment area as the original Capillus272 Pro cleared under K143199. Total "dose" – delivered energy over time - (J/cm^2) is logically reduced. Just as for Capillus272 Pro (K143199) and reference devices, there are no reported adverse events for this technology.

Substantial Equivalence

The Capillus202 is the same technology used by Capillus272 Pro (K143199) and other reference devices; specifically, Transdermal Cap (K150613). The Capillus202 is as safe and (commensurate to number of diodes) effective as the Capillus272 Pro, as well as other reference devices in its class, such as the Hairmax Lasercomb.

Capillus272 Pro	Capillus202	LaserCap LCPro
K143199	Candidate	K150613
LLLT Device Type	LLLT Device Type	LLLT Device Type
Prescription Use	Prescription Use	Prescription Application
Intended Use - Androgenic Alopecia	Intended Use - Androgenic Alopecia	Intended Use -Androgenic Alopecia
Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R	Contain Laser Diodes- Class 3R
Helmet/Cap Design	Helmet/Cap Design	Helmet/Cap Design
650nm	650nm	650nm
Marketing clearance for Females	Marketing clearance for Females	Marketing clearance for both genders
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands-Free
272 Laser Diodes	202 Laser Diodes	224 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)	Ludwig-Savin I-II (females)
Efficacy Rates - High Compared to Placebo	Efficacy Rates - High Compared to Placebo	NA
Treatment- 17weeks, every other day (indefinite)	Treatment- 17weeks, every other day (indefinite)	Treatment - 16 weeks, every otherday (indefinite)
Device Class II	Device Class II	Device Class II

Capillus LLC believes that with the exception of the configuration of the optical elements, the Capillus202 is the same device in form, function, safety, and efficacy as the previous version and the predicate device(s). The Hairmax Lasercomb, offered as a reference, is proof of the functionality and acceptability of devices with fewer laser diodes cleared by the FDA in the category of OAP, both technically and clinically. Capillus LLC 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 Capillus202 satisfies the FDA's requirements (for device modification notification) with respect to intended use, and technological and design characteristics. Additionally, no new safety or efficacy concerns are

raised due to the minor difference present between devices.

Signed:

01.13.2016

Patricia Schnoor

Quality, Safety & Compliance Manager