Capillus
Patricia Schnoor
Director, QA/RA
1715 NW 82nd Ave.
Doral, Florida 33126

September 12, 2019

Re: K192012
Trade/Device Name: Capillus 112, Capillus 244
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: Class II
Product Code: OAP
Dated: July 26, 2019
Received: July 29, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see

https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R.P. Ogden,
Assistant Director, THT4A4
DHT4A: Division of General Surgery Devices
OHT5: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192012

Device Name

CapillusX, CapillusX+

Indications for Use *(Describe)*

The CapillusX and CapillusX+ laser domes are intended to treat Androgenetic Alopecia and promotion of hair growth in males who have Norwood Hamilton Classifications of IIa to V patterns of hair loss and treating Androgenetic Alopecia and promotion of hair growth in females who have Ludwig (Savin) Scale 1-4, 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: **September10, 2019**

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: CapillusX, CapillusX+

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)
CapillusPro	Capillus LLC	163170
Capillus82	Capillus LLC	163170

Intended Use / Indications for Use:

The CapillusX and CapillusX+ 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 CapillusX and CapillusX+ consist of 112 and 244 (respectively) 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. These models are exactly the same as the (predicate) Capillus family of devices (CapillusPro, Capillus202, Capillus82) with the exception of the number of diodes.

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.

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 CapillusX and CapillusX+ 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 CapillusX and CapillusX+ the laser class of 3R which establishes the AEL (accessible emission limits) as 5 milliWatts maximum. The charger conforms to IEC 60601-1.

Just as for the currently cleared Capillus family of devices, there are no reported adverse events for this technology.

Substantial Equivalence

The Capillus devices referenced in this application are the same technology used by the LLLT devices cleared under device code OAP. The CapillusX and CapillusX+ are as safe and effective as the predicate devices, as well as other reference devices in its class.

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 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.

CapillusPro	Capillus82	CapillusX / CapillusX+
K162994	K162994	Candidate
LLLT Device Type	LLLT Device Type	LLLT Device Type
Over the Counter Use	Over the Counter Use	Over the Counter Use
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
5mW max	5mW max	5mW max
1360mW max energy	410mW max energy	560mW / 1220mW max energy
650nm	650nm	650nm
Marketing clearance for Males and Females	Marketing clearance for Males and Females	Marketing clearance for Males and Females
Passive Use-Hands Free	Passive Use-Hands Free	Passive Use-Hands Free
272 Laser Diodes	82 Laser Diodes	112 / 244 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) 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)
Efficacy Rates - High Compared to Placebo	Same as for MEP-90 (predicate)	Efficacy Rates – 35-48% (calculated)
Treatment- 17weeks, 6 min daily (indefinite)	Treatment- 6 min daily (indefinite)	Treatment- 6 min daily (indefinite)
Device Class II	Device Class II	Device Class II

For these reasons, the CapillusX and CapillusX+ satisfy the FDA's substantial equivalence requirements with respect to intended use, and 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.

Signed:

Patricia Schnoor

Director, QA/RA