December 3, 2020

Advihair S.R.L.
Angleo D'Andrea
Owner
Via Benini 11
Zola Predosa, BO 40069
Italy

Re: K193008
Trade/Device Name: Tricoglam Home Use
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 25, 2020
Received: October 15, 2020

Dear Angleo D'Andrea:

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,

Purva Pandya
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: 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)*
K193008

Device Name
Tricoglam Home USE

Indications for Use *(Describe)*
Tricoglam Home Use is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I - II, in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa - V and for both, Fitzpatrick Classification of Skin Phototypes of 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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510 (k) SUMMARY K193008

SUBMITTER INFORMATION

A. Company Name: ADVIHAIR S.R.L.

B. Company Address: Via Benini, 11, Zona industriale – 40069 Zola Predosa (BO)

C. Company Phone: +39-0517554
Company Fax:
Company e-mail: angelodandrea@cesareragazzi.it

D. Contact person: Angleo D'Andrea
Owner
ADVIHAIR s.r.l.

E. Date Summary Prepared: April 24th, 2019

DEVICE IDENTIFICATION

A. Generic Device Name: Physical Medicine Therapeutic Devices

B. Trade/Proprietary Name: TRICOGLAM HOME USE

C. Classification: Class II

D. Product Code: OAP

E. Classification Panel: 890 Physical Medicine Therapeutic Devices

F. Regulation Number: 890.5500

LEGALLY MARKETED PREDICATE DEVICE

Predicate device	510 (k) Holder	510 (k) No.	Date cleared
CAPILLUS 82	**Capillus LLC**	K151516	August 21st, 2015
DermaScalp Laser Caps (Lasercap80, Lasercap 120)	**Transdermal Cap, Inc.**	K161875	June 20th, 2018
Revian Red	**PhotonMD, Inc**	K173729	February 28th, 2018
Illumiflow Laser Cap	**Eglobal, LLC**	K162071	January 23rd, 2017

DEVICE DESCRIPTION

Tricoglam Home Use is a white and grey plastic helmet and inside is housed an electronic board with all the electrical components and a series of LED diodes on a wavelength, protected by a transparent plastic. The energy is distributed homogeneously.

This Helmet is composed by 105 red LEDs arranged uniformly inside the helmet with a wavelength of 650 nm +/- 10 nm

The program consists of the lighting of all the red diodes for a duration of 20 min in continuous (every day).

To start the treatment the user should press the button on the back and activate the program. All LEDs light up and, after the pre-set 20 minutes, all LEDs turn off.

Technical data

On the electronic board 105 LED diodes of the latest generation on one side and microelectronic components on the other are housed. The technology used is SMT (as in smartphones, computers, TV) that reduces size, weight and improves efficiency, thus ensuring lower thermal dissipation.
On average, each LED produces an optical power of over 5 mW. The viewing angle is greater than 100° and the position of each LED on the electronic board is designed to make the irradiation more homogeneous, calculating the received energy exactly for each cm2 and avoiding the strongly illuminated areas. The total irradiated optical power is greater than 0.63 J. The total continuous energy dose for a 20-minute treatment time is about 1.2 J / cm^2.
The power supply has a universal voltage input, so the device can be used anywhere without any intervention.

The home-use system is presented in a closed cardboard box without openings, on the four sides of the box are shown the images and texts of the product for the customer. Overall, the whole package is approximately 31 x 22 x 15 cm with a total weight of 1.20 kg.

The helmet is made of a white and smooth plastic and a colored border, weighs about 0.5 kg avoiding overloading the neck. The dimensions of the product are about 28x19x12 cm.
105 LED diodes equidistant on a flexible electronic board are arranged inside the helmet.

On the upper part of the helmet there are holes that allow the passage of air. During the treatment, the internal temperature undergoes a very modest increase, improving comfort for the user.
On the back of the helmet there is the power button and a standard microUSB socket, through which you can power the helmet through any latest generation USB power supply..
Inside there is a rechargeable lithium ion battery that recharges using the same USB port. In this way, treatments can also be performed without connecting the helmet to an external power supply.
Considering treatments lasting 20 minutes, the battery is able to ensure at least 2 complete treatments independently.

The maximum consumption of the helmet, considering also the recharge of the internal battery, is about 8W to 5V. The optimal operating temperature is between 16 ° C and 37 ° C.

INDICATIONS FOR USE STATEMENT

Tricoglam Home Use is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications I - II, in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa - V and for both, Fitzpatrick Classification of Skin Phototypes of I - IV.

SUBSTANTIAL EQUIVALENCE

All information provided with the present submission supports the substantial equivalence for the Tricoglam Home Use with the predicate device and its accessories that have identical characteristics and intended use and similar indication statement. In addition all clinical data and all performance tests that have been performed in accordance with the Standards for the Software Evaluation and for the Electrical and Electromagnetic Safety test, in addition to the requirements for the laser products demonstrate that Tricoglam Home Use devices have safety and effectiveness for its intended use.

The following matrix illustrates the equivalencies of the Tricoglam Home Use, as well as the substantial equivalent predicate devices.

PREDICATE DEVICES COMPARISON CHART

Table 1

COMPARISON CHART TRICOGLAM HOME USE					
	ADVIHAIR S.R.L. TRICOGLAM HOME USE New Device	**CAPILLUS LLC Capillus 82** Predicate device	**TRANSDERMAL CAP, INC.** LaserCap80 LaserCap120 Predicate device	**PHOTO MED, INC** Revian Red Predicate device	**EGLOBAL, LLC** Illumiflow Laser Cap Predicate device
"K" NUMBERS	**K193008**	**K151516**	**K161875**	**K173729**	**K162071**
Proprietary name	**Tricoglam Home Use**	**Capillus 82**	**LaserCap80 LaserCap120**	**Revian Red**	**Illumiflow Laser Cap**
CFR Section	890.5500	890.5500	890.5500	890.5500	890.5500
Pro-code	OAP	OAP	OAP	OAP	OAP
Classification name	Infrared lamp per 21 CFR 890.5500	Infrared lamp per 21 CFR 890.5500	Infrared lamp per 21 CFR 890.5500	Infrared lamp per 21 CFR 890.5500	Infrared lamp per 21 CFR 890.5500
Intended / Indications for use	Tricoglam Home Use is indicated to promote hair growth in	The Capillus82 is indicated to promote hair growth in females who	LaserCap120, and LaserCap80 are indicated to promote	Revian Red is indicated to treat Androgenetic Alopecia and	The illumiflow Laser Cap is indicated to promote hair

	females with androgenetic alopecia who have Ludwig-Savin Classifications I - II, in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa - V and for both, Fitzpatrick Classification of Skin Phototypes of I - IV.	have androgenic alopecia and Ludwig-Savin Classifications of I- II; and with Fitzpatrick Classification of Skin Phototypes I to IV.	hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I- II, males with androgenetic alopecia who have amilton-Norwood classifications Ila-Vand for both genders, Fitzpatrick Classification of Skin Phototypes I to IV	promote hair growth in males who have Norwood-Hamilton Classifications of IIa - 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 patterns of hair loss; both with Fitzpatrick Skin Types I - IV.	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.
Wearable Mounting	Helmet	Helmet/Cap Design	Helmet/Cap Design	Textile Cap	Helmet/Cap Design
Wave-Length(s) and visible light source	105 Red LEDs 650 nm +/- 10nm	82 Red Laser Diode 650 nm	Lasercap80: 80 Red Laser Diode 650 nm Lasercap120: 120 Red Laser Diode 650 nm	119 Red LEDs- 620 - 660 nm	272 Red Laser Diode 650 nm
Fluence	1,2 J / cm^2			1 J / cm^2	
Power output	525 mW	410 mW	400mW	1 J / cm^2	1.360mW
Treatment Time	20 minutes in continuous every day	Every other day 20-35 mins	2 times / week 20 mins	Every day 10 mins	Every other day 30 mins
Minimum duration of use	16 weeks	17 weeks	17 weeks	16 weeks	16 weeks

Battery	Rechargeable battery	Rechargeable battery	Rechargeable battery	Rechargeable battery	Rechargeable battery
Other Design Characteristics	after completion of time, unit powers down **Tricoglam Home Use** does **not** contain a 'safety interlock' which automatically pauses therapy if the subject's head is in a less-than-optimal position**.**	after completion of time, unit powers down	after completion of time, unit powers down	Cap pauses therapy if subject's head moves outside zone of radiation; after completion of treatment, unit powers down, limits daily treatment to 10 mins, and provides treatment reminders and messages via mobile app controller	The Illumiflow Laser Cap does **not** contain a 'safety interlock' which automatically pauses therapy if the subject's head is in a less-than-optimal position. The illumiflow Laser Cap does **not** utilize audible tones at the beginning or end of treatment.

TECHNICAL CHARACTERISTICS

A comparison of the technological characteristics of Tricoglam Home Use and the predicate devices has been performed. The results of this comparison demonstrate that the technologic characteristics and the operating principle of the Tricoglam Home Use are the same or very similar to those of the claimed predicate devices. Where any differences arise from the analysis of the predicate device characteristics and those of the device subject of this submission, the clinical data evaluated from scientific publications give scientific evidence of the safety and the effectiveness of the Tricoglam Home Use devices. The system was evaluated and found compliant with IEC 60601-1 for electrical safety, IEC 60601-1-2 for EMI/EMC, and 10993-1 for biocompatibility of the treatment tips. Verification and validation data show that the device meets all product specifications.

PERFORMANCE DATA

No clinical trial data for the Tricoglam Home Use was submitted for this 510(k).
To demonstrate substantial equivalence to the predicate device non clinical performance testing have been performed included evaluation to IEC 60601-1 and 60601-1-2 to confirm the device's electrical safety and electromagnetic compatibility and conformance with IEC 60601-1-11, IEC 60601-2-57, and IEC 62471.
Material of the helmet are biocompatible according to ISO 10993-5 and ISO 10993-10. Performance verification and validation testing demonstrates that Tricoglam Home Use meets user needs and design inputs and met requirements for its intended use.

Studies Related to Human Factors Evaluation:
Human factors evaluation of Tricoglam Home Use was considered following IEC 62366-1.

Sufficient data were obtained to show that the device is substantially equivalent to the predicate device and meets safety and effectiveness criteria.

CLINICAL DATA

The devices have been designed and validated in such a way that, when used under the conditions and for the purposes intended, it will not compromise the clinical condition or the safety of patients, or the safety and health of users or other people, provided that any risk which may be associated with its use constitute acceptable risks when weighed against the benefits to the patient and is compatible with a high level of protection of health and safety.

CONCLUSION

Based on the foregoing, the Tricoglam Home Use is substantially equivalent to the legally marketed, claimed predicate devices for the purposes of this 510 (k) submission. Safety and effectiveness were reasonably assured, justifying 510 (k) clearance.