January 30, 2018

Chongqing Peninsula Medical Technology Co., Ltd.
% Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion
No.121 Science Road, Guangzhou Science Park
Guangzhou, 51006 China

Re: K171835
Trade/Device Name: Irradiation Aesthetic Device
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: October 29, 2017
Received: November 6, 2017

Dear Ms. Lee:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

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)*
K171835

Device Name
Irradiation Aesthetic Device

Indications for Use *(Describe)*
The Irradiation Aesthetic Device (Model: HairPro) is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I - II and males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa – V and for both, 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.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 890.5500.

1. Submitter Information

Sponsor Name: Chongqing Peninsula Medical Technology Co., Ltd.
Address: No.2-4, 2F Block I, Biological and Biochemical Park, 70-1&70-2# Ke Yuan 4th Road, Jiulongpo District, Chongqing, China
Contact name: Zhang Sudi (RA)
Tel: +86-150 1257 8550
Fax: 023-6861 1963
E-mail: zsd@peninsulalaser.com

Application Correspondent:

Contact Person: Ms. Cassie Lee
Guangzhou GLOMED Biological Technology Co., Ltd.
Address: Suite 306, Kecheng Mansion, No.121 Science Road, Guangzhou Science Park, Guangzhou 510663, China
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Type of 510(k):	Traditional
Trade Name:	Irradiation Aesthetic Device
Classification Name:	Infrared Lamp
Review Panel:	General & Plastic Surgery
Product Code:	OAP
Regulation Number:	890.5500
Regulation Class:	2

3. Predicate Device Information

Sponsor: Capillus LLC

Classification Name: Infrared Lamp

Trade Name: Capillus272, Capillus202, Capillus82

510(K) Number: K153618, K160285, K163170

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 890.5500

Regulation Class: 2

4. Device Description

Irradiation Aesthetic Device (Model: HairPro) consists of laser diodes that are spread throughout the cap. The device uses diode lasers to cover the entire area of the head that is normally covered with hair, and this unique design allows the treatment of the entire scalp without manual movement.
In the process of the cap working, the indicator blinks red based on the working frequency of the laser diodes. Built-in timing function, the cap can record the time per treatment, and the cap can stop working automatically after each 30 minutes treatment. When the built-in IR detected the cap is not worn on the head, the laser light output will be automatically suspended immediately and the cap will automatically shut down after 10 minutes.

5. Intended Use

The Irradiation Aesthetic Device (Model: HairPro) is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I - II and males with androgenetic alopecia who have Norwood-Hamilton Classifications of IIa – V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.

6. Test Summary

Irradiation Aesthetic Device (Model: HairPro) has been evaluated the safety and performance by lab bench testing according to the following standards:

Standards No.	Standard Title	Version	Date	Detail
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety	2005+A1:2012	01/14/2014	Attachment 10
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential	2007	06/27/2016	Attachment 10

	performance - Collateral standard: Electromagnetic compatibility - Requirements and tests			
IEC 60825-1	Safety of laser products – Part 1: Equipment classification and requirements	Second edition:03/2007	03/2007	Attachment 10
IEC60601-1-11	Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used	2010	03/1/2011	Attachment 10
ISO 10993-5 (Cytotoxicity)	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	2009	05/05/2010	Attachment 9
ISO 10993-10 (Sensitization and Irritation)	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	03/16/2010	Attachment 9

7. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions and the applicable standards. The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device**			**Verdict**
Company	Chongqing Peninsula Medical Technology Co., Ltd.	Capillus LLC			--
Trade Name	HairPro	Capillus82	Capillus272	Capillus202	--
Classification Name	Infrared Lamp	Infrared Lamp			SE
510(k) Number	K171835	K163170	K160285	K153618	--
Product Code	OAP	OAP			SE
Intended Use / Indications for Use	The Irradiation Aesthetic Device (Model: HairPro) is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I - II and males with androgenetic	The Capillus laser domes 82, 202, 272 Pro, 272 OfficePro, 302, 312,	The Capillus272 Pro, Capillus272 OfficePro, Capillus82 and Capillus202	The Capillus202 is indicated to promote hair growth in females with Androgenet	SE

Elements of Comparison	Subject Device	Predicate Device			Verdict
	alopecia who have Norwood-Hamilton Classifications of IIa – V and for both, Fitzpatrick Classification of Skin Phototypes I to IV.	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.	are intended to treat the promote hair growth in females with Androgenetic Alopecia who have Ludwig (Savin) Scale I-II, and in males with androgenic alopecia who have Norwood Hamilton Classifications Iia-V; and both genders having Fitzpatrick Classifications of Skin Prototypes I to IV.	ic Alopecia who have Ludwig-Savin Classifications of I-II, and with Fitzpatrick Skin Types I to IV.	
Waveform	Visible red laser	Visible red laser			SE
Wavelength	650nm±5nm	650nm			SE
Amounts of Laser Lamp	81	Capillus272 Pro: 272 Capillus202: 202 Capillus82: 82			SE Note 1
Energy of per Laser Lamp	5mW ±10%	<5mW			SE Note 1
Classification according to IEC60825-1	Class 3R	Class 3R			SE
Treatment Time	Each Treatment: 30 min Total Treatment: 3 times per	Each Treatment: 30 min Total Treatment: every other day, for 17			SE Note 1

Elements of Comparison	Subject Device	Predicate Device	Verdict
	week	weeks.	
Treatment Area	202.3 cm^2 Mathematically Max. derived	Capillus272: 495.37 cm^2 Capillus202: 449.51 cm^2 Capillus82: 194.42 cm^2 Mathematically Max. derived	SE Note 1
Irradiance (power per area)	2.2022 mW/cm^2 Mathematically Max. derived	Capillus272: 2.7454 mW/cm^2 Capillus202: 2.2469 mW/cm^2 Capillus82: 2.1088 mW/cm^2 Mathematically Max. derived	SE Note 1
Fluence	3.9639 J/cm^2 Mathematically Max. derived	Capillus272: 4.9417 J/cm^2 Capillus202: 4.044 J/cm^2 Capillus82: 3.7920 J/cm^2 Mathematically Max. derived	SE Note 1
Dimension	199mm*179mm*88mm (L x W x H)	--	SE Note 2
Life Expectancy	5 years	--	SE
Weight	1000g	--	SE Note 2
Environment for Operation	Temperature: 5°C~30°C Humidity: ⩽ 80% Atmosphere range: 700hPa-1060hPa	--	SE Note 2
Environment for Storage	Temperature: 0°C~50°C Humidity: ⩽ 85% Atmosphere range: 50kPa-110kPa	--	SE Note 2
Safety Feature	Complied with IEC 60601-1 and IEC 60601-1-2	Complied with IEC 60601-1 and IEC 60601-1-2	SE
Biocompatibility Feature	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	SE

Comparison in Detail(s):

Note 1:

Although “Amounts of Laser Lamp”, “Treatment Time”, “Treatment Area”, “Irradiance (power per area)” and “Fluence” of the subject device are different from the predicate devices, however, the energy and power parameters’ range of subject device can be covered by predicate device’s several models’ range; they are very similar. So these parameters’ differences will not raise any safety or effectiveness issue.

Note 2:

"Dimension", "Weight", "Environment for Operation" and "Environment for Storage" of subject device are different from the predicate device, it will not affect the main function and the intended use of the device as they all also comply with IEC 60601-1 requirements. Besides, the subtle changes of the physical characteristics will not affect the critical functions or the normal use.

8. Conclusion

The subject device Irradiation Aesthetic Device (Model: HairPro) has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate device.

9. Summary Prepared Date

26 January 2018