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

April 4, 2017

Slinph Technologies Co., Ltd
% Cecilia Ceng
Manager
Guangzhou Glomed Biological Technology Co., Ltd.
Suite 306, Kecheng Mansion, No.121 Science Road
Guangzhou Science Park
Guangzhou, 510663 CN

Re: K162782
Trade/Device Name: Ihelmet Hair Growth System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: March 6, 2017
Received: March 9, 2017

Dear Cecilia Ceng:

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,

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)*
K162782

Device Name
iHelmet Hair Growth System (Model: LTD200S)

Indications for Use *(Describe)*
iHelmet Hair Growth System (Model: LTD200S) 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.

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."

Chapter 6. 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: Slinph Technologies Co., Ltd.
Address: Room 211, Building B, 1970 Cultural and Creative Industrial Park, Minzhi Street, Longhua, Shenzhen, China.
Contact name: Zou Jian (General Manager)
Tel: +86-158 1556 8501
Fax: 0755-83461353
Email: kevinzou@slinph.com

Application Correspondent:

Contact Person: Ms. Cecilia Ceng
Guangzhou GLOMED Biological Technology Co., Ltd.
Tel: +86-20-61099984
Email: regulatory@glomed-info.com

2. Subject Device Information

Type of 510(k):	Traditional
Common Name:	Lamp, non-heating, for promotion of hair growth
Trade Name:	iHelmet Hair Growth System
Classification Name:	Infrared lamp per 21 CFR 890.5500
Review Panel:	General & Plastic Surgery
Product Code:	OAP
Regulation Number:	21 CFR 890.5500
Regulation Class:	2

3. Predicate Device Information

Sponsor	Capillus, LLC.
Common Name	Lamp, non-heating, for promotion of hair growth
Trade Name	Capillus272, Capillus202, Capillus82
Classification Name	Infrared lamp per 21 CFR 890.5500
510(k) number	K153618, K160285, K163170
Review Panel	General & Plastic Surgery
Product Code	OAP
Regulation Number	21 CFR 890.5500
Regulation Class	2

4. Device Description

iHelmet Hair Growth System consists of laser diodes that are spread throughout the helmet. The product 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. The product will pause automatically treatment if the sensor detects that the head is not in close proximity to the sensor, and will resume again once close enough. At the end of the treatment, an audible tone beeps to indicate the treatment is over and then the helmet automatically shut off.

5. Intended Use

iHelmet Hair Growth System, Model: LTD200S is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, in 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

iHelmet Hair Growth System has been evaluated the safety and performance by lab bench testing according to the following standards:

Standards No.	Standard Title	Version	Date
IEC 60601-1	Medical Electrical Equipment - Part 1: General Requirements for Safety	2005+A1:2012	01/14/2014
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	2001+A1:2006	09/09/2008
IEC 60825-1	Safety of laser products - Part 1: Equipment classification and requirements	2007	03/2007
IEC60601-1-11	Medical Electrical Equipment - Part 1-	2010	03/1/2011

	11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems Used		
ISO 10993-5 (Cytotoxicity)	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	2009	05/05/2010
ISO 10993-10 (Sensitization and Irritation)	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	03/16/2010

Except for the tests mentioned above, we have conducted the temperature test on the iHelmet Hair Growth System to prove that the highest temperature between iHelmet Hair Growth System and scalp would not exceed 43°C during operation, which is meet the requirement of safety standard IEC 60601-1.

7. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material 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	Slinph Technologies Co., Ltd.	Capillus LLC	--
Trade Name	iHelmet Hair Growth System	Capillus272, Capillus202, Capillus82	--
Classification Name	Infrared Lamp	Infrared Lamp	--
510(k) Number	K162782	K153618, K160285, K163170	--
Product Code	OAP	OAP	SE
Intended Use / Indications for Use	iHelmet Hair Growth System (Model: LTD200S) 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.	The Capillus272, Capillus202, Capillus82 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.	SE
Waveform	Visible red laser	Visible red laser	SE
Wavelength	650nm±10nm	650nm	SE
Amounts of	200	Capillus272: 272	SE

Elements of Comparison	Subject Device	Predicate Device	Verdict
Laser Lamp		Capillus202: 202 Capillus82: 82	Note 1
Energy of per Laser Lamp	4~5mW	<5mW	SE
Classification according to IEC60825-1	Class 3R	Class 3R	SE
Treatment Time	Each Treatment: 20-35 min Total Treatment: every other day, for 16 weeks	Each Treatment: 30 min Total Treatment: every other day, for 17 weeks.	SE Note 1
Treatment Area	424.93 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)	2.3533 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	4.9420 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	266mm x 196mm x 135mm (L x W x H)	--	SE Note 2
Weight	600g	--	SE Note 2
Environment for Operation	Temperature: 15~30°C Humidity: 30~80% RH Atmosphere range: 90~110kPa	--	SE Note 2
Environment for Storage	Temperature: -20~65°C Humidity: 0~ 80% RH Atmosphere range: 50~110kPa	--	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 the “Amounts of Laser Lamp”, “Treatment Time”, “Treatment Area”, “Irradiance”, and “Fluence” of subject device and predicate device are a little difference, 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:

Although the “Weight”, “Dimensions”, “Environment for Operation”, “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 iHelmet Hair Growth System has all features of the predicate devices. The few differences do not affect the safety and effectiveness of the subject device. Thus, the subject device is substantially equivalent to the predicate devices.

9. Summary Prepared Date

2 April 2017