December 23, 2019

Slinph Technologies Co., LTD
℅ S K
Manager
SK Medical Device International Corp.
Suite 52, Floor 16, No. 119 Xing Guang Ying Jing, Shui Ying Road
Guangzhou, 51006 CN

Re: K190467
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: November 21, 2019
Received: November 25, 2019

Dear S K:

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,

Jessica Mavadia-Shukla
Acting 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190467

Device Name
iHelmet Hair Growth System, Model: LTD88Lite, LTD36Air, LTD160Pro

Indications for Use *(Describe)*
iHelmet Hair Growth System (LTD88Lite, LTD36Air, LTD160Pro) 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.

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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Chapter 6. 510(k) Summary

K190467

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)
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Email: kevinzou@slinph.com

Application Correspondent:
Contact Person: Ms. SK
Tel: +86-18620793542
Email: medical-device@qq.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

Predicate device 1

Sponsor	iHelmet Hair Growth System
Common Name	Lamp, non-heating, for promotion of hair growth
Trade Name	LTD200S
Classification Name	Infrared lamp per 21 CFR 890.5500
510(k) number	K162782
Review Panel	General & Plastic Surgery
Product Code	OAP
Regulation Number	21 CFR 890.5500
Regulation Class	2

	Predicate device 2
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: LTD88Lite, LTD36Air, LTD160Pro) 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	07/09/2014
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	Edition 4.0 2014-02	06/27/2016
IEC 60825-1	Safety of laser products - Part 1: Equipment classification and requirements	2007-03	07/09/2014
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	06/27/2016
ISO 10993-5 (Cytotoxicity)	Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity	2009	12/23/2016
ISO 10993-10 (Sensitization and Irritation)	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	2010	07/26/2016

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 1	Predicate Device 2	Verdict
Company	Slinph Technologies Co., Ltd.	Slinph Technologies Co., Ltd.	Capillus LLC	--
Trade Name	iHelmet Hair Growth System	iHelmet Hair Growth System	Capillus272, Capillus202, Capillus82	--
Classification Name	Infrared Lamp	Infrared Lamp	Infrared Lamp	--

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
510(k) Number	Applying	K162782	K153618, K160285, K163170	--
Product Code	OAP	OAP	OAP	SE
Intended Use / Indications for Use	iHelmet Hair Growth System (Model: LTD88Lite, LTD36Air, LTD160Pro) 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.	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	Visible red laser	SE
Wavelength	650nm±10nm	650nm±10nm	650nm	SE
Amounts of Laser Lamp	LTD88Lite: 88 LTD36Air: 36 LTD160Pro: 160	200	Capillus272: 272 Capillus202: 202 Capillus82: 82	SE Note 1
Energy of per Laser Lamp	4~5mW	4~5mW	<5mW	SE
Classification according to IEC60825-1	Class 3R	Class 3R	Class 3R	SE
Treatment Time	Each Treatment: 20-35 min Total Treatment: every other day, for 16 weeks	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	LTD88Lite: 220.61 cm^2 LTD36Air: 86.3 cm^2 LTD160Pro: 338.42 cm^2 Mathematically Max. derived	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	LTD88Lite: 2.3533	2.3533 mW/cm^2	Capillus272:	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Verdict
per area)	mW/cm^2 LTD36Air: 2.0857 mW/cm^2 LTD160Pro: 2.3639 mW/cm Mathematically Max. derived	Mathematically Max. derived	2.7454 mW/cm^2 Capillus202: 2.2469 mW/cm^2 Capillus82: 2.1088 mW/cm^2 Mathematically Max. derived	Note 1
Fluence	LTD88Lite: 4.1883 J/cm^2 LTD36Air: 4.3801 J/cm^2 LTD160Pro: 4.9642 J/cm^2 Mathematically Max. derived	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)	266mm x 196mm x 135mm (L x W x H)	--	SE Note 2
Weight	LTD88Lite: about 550g LTD36Air: about 500g LTD36Air: about 600g	600g	--	SE Note 2
Environment for Operation	Temperature: 15~30°C Humidity: 30~80% RH Atmosphere range: 90~110kPa	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	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	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	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

19 February 2019