December 8, 2020

Slinph Technologies Co., Ltd
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichung Road,
Huangpu District, Guangzhou, Guangdong 51006
China

Re: K202631
Trade/Device Name: iHelmet Laser Comb
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: September 6, 2020
Received: September 11, 2020

Dear Cassie 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. 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
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)*
K202631

Device Name
iHelmet Laser Comb (Model: SC8 Dual, SC12, SC16Pro)

Indications for Use *(Describe)*
The iHelmet Laser Comb is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes 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
(K202631)

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
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- Contact Person (including title): Jian Zou (General Manager)
- E-mail: Kevinzou@slinph.com

2. Application Correspondent:

- Contact Person: Ms. Cassie Lee
- Guangzhou GLOMED Biological Technology Co., Ltd.
- Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
- Tel: +86 20 8266 2446
- Email: regulatory@glomed-info.com

3. Subject Device Information

Type of 510(k):	Traditional
Trade Name:	iHelmet Laser Comb
Classification Name:	Laser, comb, hair
Review Panel:	General & Plastic Surgery
Product Code:	OAP
Regulation Number:	890.5500
Regulation Class:	2

4. Predicate Device Information

Sponsor: OMM IMPORTS INC DBA ZERO GRAVITY

Classification Name: Infrared Lamp

Trade Name: Laser Hair Therapy

510(K) Number: K183329

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 890.5500

Regulation Class: 2

5. Device Description

The iHelmet Laser Comb is a comb-shaped low level laser therapy (LLLT) device that emits laser light with the intention to promote hair growth. The device provides distributed laser to the scalp at 650+/-10nm while the comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp. The Laser Hair Therapy is designed as handheld product, and it consists of main unit, the charging dock and a power cable, as well as it is powered by the built-in rechargeable lithium battery. The device is one-button operated, and has an audible timer that automatically turns the lasers off after the treatment is completed.

6. Intended Use

The iHelmet Laser Comb is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-4, II-1, II-2, or frontal and both with Fitzpatrick Skin Phototypes I-IV.

7. Test Summary

The iHelmet Laser Comb (Model: SC8 Dual, SC12, SC16Pro) 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	07/09/2014	Attachment 9
IEC 60601-1-11	Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements for Medical Electrical Equipment and	Edition 2.0, 2015-01	06/27/2016	Attachment 9

	Medical Electrical Systems Used			
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	09/17/2018	Attachment 9
IEC 60825-1	Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]	Edition 2.0, 2007-03	07/09/2014	Attachment 9
IEC 62133-2	Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems	Edition 1.0 2017-02	12/23/2019	Attachment 9

8. Comparison to Predicate Device

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

Elements of Comparison	**Subject Device**	**Predicate Device**	**Remark**
Sponsor	SLINPH TECHNOLOGIES CO., LTD	OMM IMPORTS INC DBA ZERO GRAVITY	--
Device name	iHelmet Laser Comb (Model: SC8 Dual, SC12, SC16Pro)	Laser Hair Therapy	--
K Number	Pending	K183329	--
Product Code	OAP	OAP	SE
Classification	Class II	Class II	SE
Location for use	OTC	OTC	SE
Intended Use	The iHelmet Laser Comb is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-4, II-1, II-2, or frontal and both with	Laser Hair Therapy is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V or females with androgenic alopecia who have Ludwig-Savin Classifications of I-4, II-1, II-2, or	SE

Elements of Comparison	Subject Device	Predicate Device	Remark
	Fitzpatrick Skin Phototypes I-IV.	frontal and both with Fitzpatrick Skin Phototypes I-IV.	
Type of Laser	Visible red light-emitting diodes	Visible red light-emitting diodes	SE
Light Class	Class I	Class 3R	SE Note 1
Amount of Light-emitting diodes	For model SC8 Dual: 16 pcs For model SC12: 12 pcs For model SC16 Pro: 16 pcs	12 pcs	SE Note 2
Power	<5mW	<5mW	SE
Wavelength	For model SC8 Dual: 650nm±10nm, 624nm For model SC12: 650nm±10nm For model SC16Pro: 650nm±10nm	655±5nm	SE Note 2
Treatment time	For SC8 Dual: 11 minutes per treatment, 3 times per week (every other day) For SC12: 8 minutes per treatment, 3 times per week (every other day) For SC16Por: 6 minutes per treatment, 3 times per week (every other day)	8 minutes per treatment, 3 times per week (every other day)	SE Note 2
Applicable people	Norwood- Hamilton IIa~V (males); Ludwig-Savin I-4, II-1, II-2, or frontal (females)	Norwood- Hamilton IIa~V (males); Ludwig-Savin I-4, II-1, II-2, or frontal (females)	SE
Applicable skin	Fitzpatrick Skin Phototypes I- IV	Fitzpatrick Skin Phototypes I- IV	SE
Appearance design	Comb	Comb	SE
Safety	Complied with: IEC 60601-1-2; IEC 60601-1; IEC 60601-1- 11; IEC 60825-1	Complied with: IEC 60601-1-2; IEC 60601-1; IEC 60601-1- 11; IEC 60825-1	SE
Biocompatibility	Complied with: ISO 10993-5; ISO 10993-10	Complied with: ISO 10993-5; ISO 10993-10	SE Note 3

Comparison in Detail(s):

Note 1:

Although the “Light Class” of the subject device is different from the predicate device, they all meet the IEC 60825-1 requirements. So the differences will not raise any safety or effectiveness issue.

Note 2:

Although the “Amount of Light-emitting diodes”, “Wavelength” and “Treatment time” of the subject device are slightly different from the predicate device’s, they are very similar to the predicate

device and comply with the regulation requirements, so the differences will not raise any safety or effectiveness any issue.

Note 3:

The iHelmet Laser Comb is contact directly with the scalp and skin of human body and the contact duration is less than 24 hours. All materials of the iHelmet Laser Comb (Model: SC8 Dual, SC12, SC16Pro) is identical to the materials of the iHelmet Hair Growth System (K162782), the formulation and processing of them also identical and there are no other chemicals have been added to the iHelmet Laser Comb (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents, etc.).

So, they are complied with biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization).

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for In Vitro Cytotoxicity;
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

Finial Conclusion:

The subject device “iHelmet Laser Comb (Model: SC8 Dual, SC12, SC16Pro)” 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 K183329.

9. Summary Prepared Date 5 December 2020