May 12, 2022

Kam Yuen Plastic Products Ltd.
℅ Jett Lee
Regulation Manager
Guangdong Jianda Medical Technology Co Ltd
906 Room, Longxiang Garden, Tianhe District
Guangzhou, Guangdong
China

Re: K213025
Trade/Device Name: Laser hair growth helmet
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: April 9, 2022
Received: April 12, 2022

Dear Jett 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
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)*
K213025

Device Name
Laser hair growth helmet (Model: A-800)

Indications for Use *(Describe)*
The Laser hair growth helmet (Model: A-800) is intended for the promotion of hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I-II, and in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa-V; and both genders having Fitzpatrick Classification of 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.

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

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Date of the summary prepared: May 11, 2022

510(k) Summary

510(k) number: K213025

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92. This is a traditional 510(K) submission with no previous application.

1. Submitter's Information

Sponsor

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- E-mail: kamyuen@kyplastic.com

Application Correspondent:

Guangdong Jianda Medical Technology Co Ltd
Address: 906 Room, Longxiang Garden, Tianhe district, Guangzhou, China
Contact Person: Mr. Jett Lee
Title: Regulation Manager
Tel: +86-13512755282
Email: jianda-lee@foxmail.com

2. Subject Device Information

- Trade Name: Laser hair growth helmet
- Model: A-800
- Common Name: Laser, comb, hair
- Classification name: Infrared lamp per 21 CFR 890.5500
- Review Panel: General & Plastic Surgery
- Product Code: OAP

- Regulation Class: 2
- Regulation Number: 21 CFR 890.5500

3. Predicate Device Information

	Predicate Device I	Predicate Device II	Reference Device
510(k) Number	K193008	K190467	K173678
Device Name	Tricoglam Home Use	iHelmet Hair Growth System	Diode Laser Cap
Product Code	OAP	OAP	OAP
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500
Regulation Class	2	2	2

2. Device Description

The Laser hair growth helmet (Model: A-800) is hands-free, portable, non-invasive, low-level laser device, which consists of red visible light diode lasers, to produce red light operating at 650nm wavelength (maximum output power of each is 5mW). The laser sources are arranged in a dot matrix arrangement in the inner of the helmet, which could take into account of every hair follicle and promote rapid hair growth. The device will automatically suspend the work if it is removed from scalp, and the power blue light indicator flashes.

3. Indications for Use

The Laser hair growth helmet (Model: A-800) is intended for the promotion of hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I-II, and in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa-V; and both genders having Fitzpatrick Classification of Skin Phototypes I-IV.

4. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, and intended use of Laser hair growth helmet, model: A-800 is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Substantial Equivalence Comparison Table for A-800				
Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**	**Reference Device**
510(k) Number	TBD	K193008	K190467	K173678
Device Name	Laser hair growth helmet A-800	Tricoglam Home Use	iHelmet Hair Growth System	Diode Laser Cap
Product Code	OAP	OAP	OAP	OAP
Regulation Number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500
Regulation Class	2	2	2	2
LLLT Device Type	LLLT	LLLT	LLLT	LLLT
Prescription	OTC	prescription use	OTC	OTC
Intended Use	The Laser hair growth helmet (Model: A-800) is intended for the promotion of hair growth in females with androgenic alopecia who have Ludwig-Savin Classifications I-II, and in males with androgenetic alopecia who have Norwood Hamilton Classifications IIa-V; and both genders having Fitzpatrick Classification of Skin Phototypes I-IV.	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.	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.	Diode Laser Cap 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-II and both with Fitzpatrick Skin Phototypes I-IV.
Wavelength	650nm±10nm	650nm±10nm	650nm±10nm	650nm
Laser radiation output	5mW	5mW	4~5mW	≤5mW
Fluence	3.03J / cm^2	1.2 J / cm^2	LTD88Lite: 4.1883 J/cm^2 LTD36Air: 4.3801 J/cm^2 LTD160Pro: 4.9642 J/cm^2	--

Substantial Equivalence Comparison Table for A-800				
Elements of Comparison	**Subject Device**	**Predicate Device I**	**Predicate Device II**	**Reference Device**
			Mathematically Max. derived	
Amount of laser diodes	180	105	LTD88Lite: 88 LTD36Air: 36 LTD160Pro: 160	COSMO-010: 272 COSMO-020: 148 COSMO-030: 272
Irradiation over the treatment area	2.02 mW/cm^2	/	LTD88Lite: 2.3533 mW/cm^2 LTD36Air: 2.0857 mW/cm^2 LTD160Pro: 2.3639 mW/cm^2 Mathematically Max. derived	--
Classification according to IEC60825-1	Class 3R	Class 3R	Class 3R	Class 3R
Treatment Time	Each Treatment: 25 min Total Treatment: every two days	16weeks, 20 minutes in continuous every day	Each Treatment: 20-35 min Total Treatment: every other day, for 16 weeks	Each treatment: 30min 16 weeks, every other day
Appearance Design	Helmet cap	Helmet	Helmet	Helmet
Safety and Performance Feature	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60825-1, IEC 60601-1-11	Complied with IEC 60601-1, IEC 60601-1-2	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1
Biocompatibility	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	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10

5. Summary for clinical test

Clinical performance is not deemed necessary.

6. Performance Test Summary

The Laser hair growth helmet has been evaluated for its safety and performance by lab bench testing as following:

- Electrical safety and performance test according to IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005 MOD) and IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements [Including: Technical Corrigendum 1 (2008) Interpretation Sheet 1 (2007) Interpretation Sheet 2 (2007)]
- Electromagnetic compatibility test according to IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- Biocompatibility test according to ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity and ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- Software verification and validation test according to the requirements of the FDA “Guidance for Premarket Submissions and for Software Contained in Medical Devices”

7. Conclusion

The subject device Laser hair growth helmet (A-800) has all features of the predicate devices for intended use. Thus, the subject device is substantially equivalent to the predicate devices.