April 29, 2025

Dongguan Boyuan Intelligent Technology Co., Ltd.
% Reanny Wang
General Manager
Shenzhen Reanny Medical Devices Management Consulting Co.Ltd
Room 1509, Jingting Building, Dongzhou Community,
Guangming Street, Guangming District
Shenzhen, Guangdong 518107
China

Re: K250308
Trade/Device Name: Hair Growth Device (KCA441-200, KCA441-120, KCA441-88, KCA441-56, KCA441-200S, KCA441-120S, KCA441-88S, KCA441-56S, KCA451-200, KCA451-120, KCA451-88, KCA451-56, KCA451-200S, KCA451-120S, KCA451-88S, KCA451-56S)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: January 27, 2025
Received: February 3, 2025

Dear Reanny Wang:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.04.29 15:17:28 -04'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K250308

Device Name
Hair Growth Device (KCA441-200, KCA441-120, KCA441-88, KCA441-56, KCA441-200S, KCA441-120S, KCA441-88S, KCA441-56S, KCA451-200, KCA451-120, KCA451-88, KCA451-56, KCA451-200S, KCA451-120S, KCA451-88S, KCA451-56S)

Indications for Use *(Describe)*
Hair Growth Device is indicated to promote hair growth in females with androgenetic alopecia who have Ludwig-Savin Classifications of I-II, in males with and rogenetic 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.

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510(k) number: K250308

1. Information of Submitter and Correspondent

Submitter's information:

Company Name:	Dongguan Boyuan Intelligent Technology Co., Ltd.
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Date Prepared: Apr. 28, 2025

Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd

Address: Room 1509, Jingting Building, Dongzhou Community, Guangming Street, Guangming District, Shenzhen 518107, China

Contact Person: Reanny Wang

E-mail: reanny@reanny.com

Phone: +86(755) 27391220

2. Device Information

Trade Name:	Hair Growth Device
Model:	KCA441-200, KCA441-120, KCA441-88, KCA441-56, KCA441-200S, KCA441-120S, KCA441-88S, KCA441-56S, KCA451-200, KCA451-120, KCA451-88, KCA451-56, KCA451-200S, KCA451-120S, KCA451-88S, KCA451-56S
Common Name:	Laser, Comb, Hair

Classification Name: Infrared lamp

Regulation: 21 CFR 890.5500

Device Class: Class 2

Product Code: OAP

3. Identification of Predicate Device(s)

Substantial equivalent devices	Sponsor	Trade Name	510(k) number	Product Code	Regulation Number	Approval Date
Predicate device	Slinph Technologies Co., Ltd.	iHelmet Hair Growth System	K162782	OAP	21 CFR 890.5500	April 4, 2017
Reference device	DermaScalp LLC	DermaScalp Laser Caps	K173846	OAP	21 CFR 890.5500	March 21, 2018
Reference device	PhotonMD, Inc	REVIAN RED	K173729	OAP	21 CFR 890.5500	February 28, 2018

4. Description of Device

The product is composed of main unit, USB cable, and silicone pad. The main unit consists of laser diodes that are spread throughout the helmet.

Low-energy laser therapy (LLLT) is a safe and effective treatment for androgenic alopecia (AGA). The Hair Growth Device employs intelligent LLLT technology, utilizing a 650 nm, 5-milliwatt low-energy laser that penetrates the scalp surface to a depth of 3-5 mm, reaching the hair follicles.

Hair Growth Device is a small over-the-counter, portable, noninvasive, low-level laser device intended to treat Androgenetic Alopecia (Hair Loss) and to promote hair growth in Males and Females. 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. Hair Growth Device consists of main unit, USB cable and silicone strap **and no communication function**. The device will then turn on and you'll hear an audible beep.

5. Indications for Use

Hair Growth Device 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. Discussion of Comparison to Predicate Devices.

The Hair Growth Device submitted in this 510(k) submission is compared in intended use, technological characteristics and performance to the cleared iHelmet Hair Growth System **K162782**, DermaScalp Laser Caps **K173846** and REVIAN RED **K173729**.

Device	Subject device	Primary Predicate device	Primary reference device	Primary reference device	Comparison
Manufacturer	Dongguan Boyuan Intelligent Technology Co., Ltd.	Slinph Technologies Co., Ltd.	DermaScalp LLC	PhotonMD, Inc	NA
510(K) number	Pending	K162782	K173846	K173729	NA
Product name	Hair Growth Device	iHelmet Hair Growth System	DermaScalp Laser Caps	REVIAN RED	NA
Classification	Class II Device, OAP (21 CFR890.5500)	Class II Device, OAP (21 CFR890.5500)	Class II Device, OAP (21 CFR890.5500)	Class II Device, OAP (21 CFR890.5500)	Same
Classification Name	Infrared Lamp	Infrared Lamp	Infrared Lamp	Infrared lamp	Same
Indications for Use (IFU)	Hair Growth Device 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.	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 family of DermaScalp Laser Cap devices are indicated to treat Androgenetic Alpopecia 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.	REVIAN RED is indicated to treat Androgenetic Alopecia and promote hair growth in males who have Norwood-Hamilton Classifications of IIa - 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 patterns of hair loss; both with Fitzpatrick Skin Types I - IV.	Same
Model	KCA441-200, KCA441-120, KCA441-88, KCA441-56, KCA441-200S, KCA441-120S,KCA441-88S, KCA441-56S, KCA451-200, KCA451-120, KCA451-88, KCA451-56, KCA451-200S, KCA451-120S, KCA451-88S, KCA451-	LTD200S	--	---	NA

Device	Subject device		Primary Predicate device	Primary reference device	Primary reference device	Comparison
	56S					
OTC or Rx	OTC		OTC	OTC	OTC	Same
Classification Product Code	OAP		OAP	OAP	OAP	Same
Waveform	Visible red laser		Visible red laser	119 Red LEDs	119 Red LEDs	Same
Wavelength	650nm±20nm		650nm±10nm	650 nm	620 - 660 nm	Same
Amounts of Laser Lamp	56, 88, 120, 200		200	50, 80, 120, 148, 180, 202, 224, 272	51, 80	Minor different Note 1
Energy of per Laser Lamp	5mW		4~5mW	< 5mW	--	Same
Classification according to IEC60825-1	Class 3R		Class 3R	Class 3R	Class 3R	Same
Treatment Time	Each Treatment: 30 minutes. Total Treatment: once every 2 days, for 16 weeks		Each Treatment: 20-35 min Total Treatment: every other day, for 16 weeks	Treatment - 17weeks, every other day (indefinite)	--	Minor different Note 1
Treatment Area	390cm² Mathematically Max. derived		424.93 cm2 Mathematically Max. derived	--	--	Minor different Note 1
Irradiance (power per area)	2.56mw/cm² Mathematically Max. derived		2.3533 mW/cm2 Mathematically Max. derived	--	1.67 mW/cm²	Minor different Note 1
Fluence	KCA441-200, KCA451-200, KCA441-200S, KCA451-200S	4.62J/cm²;	4.9420 J/ cm2 Mathematically Max. derived	--	--	Minor different Note 1
	KCA441-88, KCA451-88, KCA441-120S, KCA451-120S	2.03J/cm²				

Device	Subject device		Primary Predicate device	Primary reference device	Primary reference device	Comparison
	KCA441-120, KCA451-120: KCA441-88, SKCA451-88S	2.77J/cm²;				
	KCA441-56, KCA451-56, KCA441-56S, KCA451-56S	1.29J/cm²				
Dimension	KCA441size: 26cm x 21cm x 12.5cm KCA451size: 26cm x 21cm x 13cm		266mm x 196mm x 135mm (L x W x H)	--	Height: 15.87 cm (6.25 in) x Width: 20 cm (7.87 in) x Length: 22.86 cm (9 in)	Minor different Note 2
Weight	KCA441 size:572g KCA451 size: weight:567g		600g	--	155 g	Minor different Note 2
Environment for Operation	Temperature: 5℃~40℃ Humidity: ≤90%RH Atmosphere range: 80~110kPa		Temperature: 15~30°C Humidity: 30~80% RH Atmosphere range: 90~110kPa	--	5-35˚C (41-95˚F) Humidity: Up to 90%, non-condensing Atmospheric Pressure: 700 hPa to 1060 hPa	Minor different Note 3
Environment for Storage	Temperature: -20℃~55℃ Humidity: ≤93%RH Atmosphere range: 50~110kPa		Temperature: -20~65°C Humidity: 0~ 80% RH Atmosphere range: 50~110kPa	--	Temperature: 15-35˚C (59-95˚F) Humidity: Up to 90%, non-condensing Atmospheric Pressure: 700 hPa to 1060 hPa	Minor different Note 3
Standards	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-1-11 ISO 10993-5 ISO 10993-10		IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-1-11 ISO 10993-5 ISO 10993-10	IEC 60601-1 IEC 60601-1-2 IEC 60825-1 IEC 60601-1-11 ISO 10993-5	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-57 ISO 10993-1 IEC 62366-1 IEC 60601-1-6	Minor different Note 4

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:

The Dimensions and Weigh of subject device, predicate devices and reference devices are difference, but they belong to portable device, only the size, weight and service life are difference, they are both complied with IEC 60601-1, so the differences do not affect the safety and effectiveness.

Note 3:

The “Operating environment” and “Transportation & Storage environment” of subject devices may be differ from the predicate devices and reference devices, but they are both compliance with the IEC 60601-1 and IEC 60601-1-11 standards, so the difference will not raise any safety or effectiveness issue.

Note 4:

They are both complied with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11 and ISO 10993-1. IEC 60601-2-57 is for non-laser light source equipment, so the difference will not raise any safety or effectiveness issue.

Conclusions:

The subject device Hair Growth Device (Model: KCA441-200, KCA441-120, KCA441-88, KCA441-56, KCA441-200S, KCA441-120S, KCA441-88S, KCA441-56S, KCA451-200, KCA451-120, KCA451-88, KCA451-56, KCA451-200S, KCA451-120S, KCA451-88S, KCA451-56S) has been compared with iHelmet Hair Growth System (K162782), DermaScalp Laser Caps (K173846) and REVIAN RED (K173729). The subject device has same intended use, similar technological characteristics as that of predicate devices and reference devices. Although there are several specifications that are different between the subject device, predicate devices and reference devices, the comparison analysis has been completed to demonstrate that the differences between these parameters would not adversely impact the safety and effectiveness of the subject device. The subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the differences between the subject device, the predicate devices and reference devices do not raise any concerns with respect to substantial equivalence. The subject device is substantially equivalent to the predicate devices.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

7.1 Non-clinical testing

A series of safety and performance tests were conducted on the subject device.

- Product service life
- Software validation_
- Biocompatibility evaluation
- Electromagnetic compatibility and electrical safety
- Safety of laser products
- Performance test

All the test results demonstrate Hair Growth Device meets the requirements of its pre-defined acceptance criteria and intended use, and it is substantially equivalent to the predicate devices.

7.2 Clinical Testing

No clinical test data was used to support the decision of substantial equivalence.

8. Conclusions

The results of the tests described above demonstrate that Hair Growth Device is as safe and effective as the predicate devices and supports a determination of substantial equivalence.