June 17, 2025

Shenzhen Kaiyan Medical Equipment Co., Ltd
Alain Dijkstra
CEO
Building#3 and Building#5, 40th of Fuxin Street
Huaide Community Fuyong Town Baoan District
Shenzhen, Guangdong 518103
China

Re: K251017
Trade/Device Name: CurrentBody Skin Dual Light Hair Growth Helmet (model: MZ-07A)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: March 31, 2025
Received: April 2, 2025

Dear Alain Dijkstra:

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: 2025.06.17 15:35:14 -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)*
K251017

Device Name
CurrentBody Skin Dual Light Hair Growth Helmet (model: MZ-07A)

Indications for Use *(Describe)*
The CurrentBody Skin Dual Light Hair Growth Helmet is indicated to promote hair growth in males with who have Norwood-Hamilton classifications of IIa-V or females with who have Ludwig-Savin Classifications of I-II 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.

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

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K251017 - 510(k) Summary

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter Information

Sponsor Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
Establishment Registration Number: 3011644607
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
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Contact Person (including title): Alain Dijkstra (CEO)
E-mail: regulation@kaiyanmedical.com

Distributor

Company Name: CurrentBody.com Ltd

Address: Q17, Crossley Road, Stockport, Greater Manchester, SK4 5BB United Kingdom

Application Correspondent:

Contact Person: Mr. Alain Dijkstra
Company: Shenzhen Kaiyan Medical Equipment Co., Ltd
Address: Building#3 and Building#5, 40th of Fuxin Street, Huaide Community Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China
Tel: +86 755 82129361
Fax: +86 755 25024651
Email: regulation@kaiyanmedical.com

2. Summary Prepared Date

23 May 2025

3. Subject Device Information

Trade Name: CurrentBody Skin Dual Light Hair Growth Helmet

Model: MZ-07A

Common Name: Laser, Comb, Hair

Classification Name: Infrared Lamp

Review Panel: General & Plastic Surgery

Product Code: OAP

Regulation Number: 21 CFR 890.5500

Regulation Class: II

4. Predicate Device Information

Primary Predicate Device Information

Sponsor: Nature Incredible Inc.

Trade Name: Neuhat Hair Growth System (or ibeauty.com Laser Cap)

Model: NEU300, NEU180

510(k) Number: K231153

Review Panel: General & Plastic Surgery

Regulatory Class: Class II

Regulatory Code: OAP

Regulation: 21 CFR 890.5500

Reference device

Sponsor: Ronald E. Berglund, GRACE Consulting, LLC

Trade Name: Bosley Booster 128 Laser Cap; Bosley Booster 162 Laser Cap; Bosley Booster 288 Laser Cap

Model: 128 model, 162 model, 288 model

510(k) Number: K240456

Review Panel: General & Plastic Surgery

Regulatory Class: Class II

Regulatory Code: OAP

Regulation: 21 CFR 890.5500

5. Device Description

The CurrentBody Skin Dual Light Hair Growth Helmet (model:MZ-07A) is an over-the-counter device designed to promote hair growth in males who have Norwood-Hamilton Classifications of IIa-V patterns of hair loss and to promote hair growth in females who have Ludwig-Savin Classifications of I-II; both with Fitzpatrick Skin Types I-IV.

The device consists of 100 laser diodes with wavelength at 655±5nm, and 200 red light diodes with wavelength at 660±5nm.

The CurrentBody Skin Dual Light Hair Growth Helmet includes a hair-growing cap, a device base and a USB power cord. There are LEDs and lasers diodes inside the cap to emit visible red light, the device base acts as a support when the device is not used. There is a power button on cap to turn on/off the device, a digital display to show the remaining treatment time, an power indicator to show charging status and a USB port for charging.

The treatment parameter is pre-set by manufacturer, the device will auto off after treatment.

6. Intended Use

The CurrentBody Skin Dual Light Hair Growth Helmet is indicated to promote hair growth in males with who have Norwood-Hamilton classifications of IIa-V or females with who have Ludwig-Savin Classifications of I-II and both with Fitzpatrick Skin Phototypes I-IV.

7. Comparison to Predicate Device

Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions 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	Primary predicate	Reference device	Verdict
Company	Shenzhen Kaiyan Medical Equipment Co., Ltd	Nature Incredible Inc.	Ronald E. Berglund, GRACE Consulting, LLC	--
Trade Name	CurrentBody Skin Dual Light Hair Growth Helmet	Neuhat Hair Growth System (or ibeauty.com Laser Cap)	Bosley Booster 128 Laser Cap; Bosley Booster 162 Laser Cap; Bosley Booster 288 Laser Cap	--
510(k) Number	Applying	K231153	K240456	--
Regulation number	21 CFR 890.5500	21 CFR 890.5500	21 CFR 890.5500	Same
Classification Name	Infrared Lamp	Infrared Lamp	Infrared Lamp	Same
Product Code	OAP	OAP	OAP	Same
Class	II	II	II	Same

Elements of Comparison	Subject Device	Primary predicate	Reference device	Verdict
Intended Use / Indications for Use	The CurrentBody Skin Dual Light Hair Growth Helmet 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 to IV.	Neuhat Hiar Growth System is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with addrogneic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I-IV. ibeauty.com Laser Cap is indicated to promote hair growth in males with androgenic alopecia who have Norwood-Hamilton classifications of IIa-V and females with addrogneic alopecia who have Ludwig-Savin Classifications of I-II and Fitzpatrick Classification of Skin Phototypes I-IV.	Indicated to promote hair growth in males with androgenetic alopecia who have Hamilton-Norwood Classifications of IIa-V and females with androgenetic alopecia who have Ludwig-Savin Classifications of I – II and Fitzpatrick Classification of Skin Phototypes I to IV.	Same
Location for use	OTC	OTC	OTC	Same
Intended User	Both sex	Both sex	Both sex	Same
Type of light	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light emitting diodes	Low-level laser diodes and light-emitting diodes	Same
Wavelength	Laser: 655 ±5nm LED: 660 ± 5nm	Laser: 655nm Red light LED: 650nm	650nm	Similar Note1
Number of diodes	Laser diodes: 100 LED diodes: 200	NEU300 Laser diodes: 100 LED diodes: 200 NEU180 Laser diodes: 50 LED diodes: 130	288 model: 115 LDs, 173 LEDs	Same

Elements of Comparison	Subject Device	Primary predicate	Reference device	Verdict
Energy of per laser diode	5 mw	5mw	5mW per light	Same
Distribution	Uniform	Not public available	Uniform	Same
Treatment Time	Every day 20 mins	Each treatment: 25 mins Total Treatment: 16 weeks, every other day (indefinite)	25 minutes every day	Same Note 2
Irradiance	2.85 mw/cm^2	Not public available	2.47 mw/cm^2	Same Note 2
Applicable people	Norwood-Hamilton IIa~V (males); Ludwig-Savin I~II (females)	Norwood-Hamilton IIa~V (males); Ludwig-Savin I~II (females)	Norwood-Hamilton IIa~V (males); Ludwig-Savin I~II (females)	Same
Applicable skin	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Fitzpatrick Skin Phototypes I-IV	Same
Helmet/Cap design	Yes	Yes	Yes	Same
Biocompatibility feature	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	All body-contacting materials are complied with ISO10993-5 and ISO 10993-10	Not public available	Same

Comparison in Detail(s):

Note 1:

Though the wavelength of subject device is a little different from predicate devices, it is very close to predicate devices. Therefore, this slight difference will not raise any effectiveness or safety issue.

Note 2:

The treatment time and irradiance of the subject device are a little difference from the predicate devices but very close. Therefore, this slight difference will not raise any effectiveness or safety issue.

8. Test Summary

7.1 Summary of Non-Clinical Performance Testing

1） Performance Testing Summary

The CurrentBody Skin Dual Light Hair Growth Helmet (Model: MZ-07A) has been evaluated the safety and performance by lab bench testing as following:

Standards No.	Standard Title	Version	Recognition Number
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	Edition 3.2 2020-08	19-49
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 medical electrical systems used in the home healthcare environment	Edition 2.1 2020-07	19-38
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	Edition 4.1 2020-09	19-36
IEC TS 60601-4-2	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	IEC TS 60601-4-2: Edition 1.0 2024-03	19-50
IEC 60601-2-57	Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic diagnostic monitoring and cosmetic/aesthetic use	Edition 2.0 2023-07	12-355
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	12-273

Standards No.	Standard Title	Version	Recognition Number
IEC 62471	Photobiological safety of lamps and lamp systems	First edition 2006-07	12-249
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	19-33

2) Biocompatibility

The patient directly contracting materials in the subject device are showed in the following list.

Components of Subject Device	Material of Components	Body Contact Category (ISO 10993-1)	Contact Duration (ISO 10993-1)
Inner surface of cap	Silicone	Surface-contacting device: skin	A-limited(<24h)

The Nature of body contact is Surface medical device-Intact skin contact. And the contact duration is less than 24 hours. According to Table 1 - Initial evaluation tests for consideration in ISO 10993-1, the applicable biological effect is:

- Cytotoxicity
- Irritation or intracutaneous reactivity
- Sensitization

The inner surface of cap (silicone) is identical to cleared device K230336 in formulation, processing, and cleaning, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents. Etc.).

3) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA'S Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level concern, since a malfunction of, or a latent design flaw in, the Software Device leads to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

4) Cybersecurity

The subject device no any external interfaces, according to FDA guidance "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices", no need cybersecurity evaluation.

7.2 Clinical Performance

Clinical testing was not needed for this 510(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

9. Conclusion

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated device K231153 and K240456.