November 1, 2024

Shenzhen Breo Technology Co., Ltd.
% Jie Yang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K242620
Trade/Device Name: Breo Laser Hair Growth Comb (Scalp 3L)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP, ISA
Dated: September 3, 2024
Received: September 3, 2024

Dear Jie Yang:

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,

Yan Fu -S
Digitally signed by Yan Fu -S
Date: 2024.11.01 13:03:09 -04'00'

for

Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242620

Device Name
Breo Laser Hair Growth Comb (Scalp 3L)

Indications for Use *(Describe)*
Breo Laser Hair Growth Comb is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) Summary - K242620

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2024/10/28

1. Submission sponsor

Name: Shenzhen Breo Technology Co., Ltd.
Address: 19/F Hisense Southen Building No.1777, Chuangye Road, Nanshan District, Shenzhen, Guangdong, 518054, China
Contact person: Zhou Yong
Title: Regulatory engineer
E-mail: Zhouy@breo.com
Tel: 0755-82073336

2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
Address: Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P.R. China
Contact person: Yang Jie
E-mail: yangjie@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Breo Laser Hair Growth Comb
Model	Scalp 3L
Common Name	Laser therapy hair growth comb
Regulatory Class	Class II
Classification	21CFR890.5500 / Infrared lamp / OAP 21CFR 890.5660/ Therapeutic massager/ ISA
Submission type	Traditional 510(K)

4. Predicate Device

510(k) number: K230134
Product name: Laser Therapy Hair Growth Comb, Lasercomb-001
Product code: OAP, ISA

5. Device Description

Breo Laser Hair Growth Comb is a hand-held comb-shaped low level laser therapy device that emits laser light designed to promote hair growth in women and men. The device provides distributed laser light to the scalp while the comb teeth simultaneously part the user's hair to ensure the laser light reaches the user's scalp.

The device also has a massage function which is a mechanical vibration function.

6. Intended use & Indication for use

Breo Laser Hair Growth Comb is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to IV.

7. Comparison to the Predicate Device

Features	**Subject Device** Breo Laser Hair Growth Comb Scalp 3L	**Predicate Device** Laser Therapy Hair Growth Comb Lasercomb-001	**Comparison**
K Number	K242620	K230134	/
Classification name	Infrared Lamp	Infrared Lamp	Same
Product code	OAP,ISA	OAP,ISA	Same
Intended use/Indications for Use	Breo Laser Hair Growth Comb is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to IV.	Laser Therapy Hair Growth Comb is indicated to treat Androgenetic Alopecia, and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Types I to IV.	Same
Location for use	OTC application	OTC application	Same
Type of laser	Visible red light-emitting diodes	Visible red light-emitting diodes	Same
Wavelength	650nm±10nm	650nm±10nm	Same
Amount of laser diodes	7	7	Same
Energy of per laser diode	4.89 mW＜ 5mW	4.63 mW, 4.56 mW, 4.66 mW, 4.78 mW, 4.86 mW, 4.78 mW,	Same

Features	**Subject Device** Breo Laser Hair Growth Comb Scalp 3L	**Predicate Device** Laser Therapy Hair Growth Comb Lasercomb-001	**Comparison**
		4.89 mW＜ 5mW	
Classification according to IEC60825-1	Class 3R	Class 3R	Same
Treatment time	15 min per treatment	15 min per treatment	Same
Treatment frequency	3 times per week, spaced out every other day, as little as 16 weeks	3 times per week, spaced out every other day, as little as 16 weeks	Same
Applicable people	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	Same
Shape design	Comb	Comb	Same
Safety feature	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC 62133 (Battery pack)	Complied with IEC60601-1, IEC60601-1-11, IEC60601-1-2 and IEC60825-1 Complied with IEC 62133 (Battery pack)	Same
Biocompatibility	All body contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23.	All body contacting materials are complied with ISO10993-5 and ISO 10993-10, ISO 10993-23.	Same

8. Non-clinical tests

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the subject device was evaluated in accordance with the FDA guidance “Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC safety testing was performed to, and passed, the following standards:

- ANSI AAMI ES60601-1:2005/A1:2012+A2:2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015+A1:2020 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
- IEC 60601-1-2:2014+A1:2020 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility Requirements and tests

In addition, testing to IEC 60825-1:2014 certifies the laser system to classification 3R, which is the same as the predicate devices.

The battery conforms to IEC 62133-2:2017/AMD1:2021.

9. Clinical study

Not applicable.

10. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the subject device is substantially equivalent to the predicate device.