April 5, 2023

Light Tree Ventures Europe B.V.
Alain Dijkstra
Manager
Laan van Ypenburg 108, 2497 GC
Hague,
Netherlands

Re: K230336
Trade/Device Name: CurrentBody Skin™ Led Hair Regrowth(Model: MZ-07)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: January 18, 2023
Received: February 7, 2023

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 (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,

Colin K. Chen -S

for

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230336

Device Name
CurrentBody Skin™ Led Hair Regrowth (Model: MZ-07)

Indications for Use *(Describe)*
The CurrentBody Skin™ Led Hair Regrowth (MZ-07) is indicated to treat Androgenetic Alopecia and to 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.

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 for K230336

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: Light Tree Ventures Europe B.V.
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Contact name: Alain Dijkstra (Manager)
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Manufacture

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

Distributor

Company Name: CurrentBody.com Ltd

Address: Unit D6, Stanley Green Business Park, Commercial Avenue, Cheadle Hulme, Cheshire, SK8 6QH

Application Correspondent:

Contact Person: Alain Dijkstra
Light Tree Ventures Europe B.V.
Address: Laan van Ypenburg 108, 2497 GC, The Hague, The Netherlands
Tel: +86-135-10378748
Email: regulation@kaiyanmedical.com

2. Summary Prepared Date

29 March 2023

3. Subject Device Information

Trade Name: CurrentBody Skin™ Led Hair Regrowth

Model: MZ-07

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

Sponsor: PhotonMD, Inc.
Common Name: Laser, Comb, Hair
Classification Name: Infrared Lamp
Trade Name: Revian Red
510(K) Number: K173729
Review Panel: General & Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

5. Device Description

The CurrentBody Skin™ Led Hair Regrowth, model: MZ-07 is an over-the-counter light-emitting diode (LED) device designed to promote hair growth in women and men by exposing the entire scalp to the photostimulation of visible red light-emitting diodes at 660nm.
The CurrentBody Skin™ Led Hair Regrowth includes a hair-growing cap, a device base and a USB power cord. The user turns on the device and then wears the device on his/her head, and the device will turn off automatically after a 10-minute treatment default.

6. Intended Use

The CurrentBody Skin™ Led Hair Regrowth (MZ-07) is indicated to treat Androgenetic Alopecia and to 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.

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	Predicate Device	Verdict
Company	Light Tree Ventures Europe B.V.	PhotonMD, Inc.	--
Trade Name	CurrentBody Skin™ LED Hair Regrowth	Revian Red	--
510(k) Number	K230336	K173729	--
Regulation number	21 CFR 890.5500	21 CFR 890.5500	Same
Classification Name	Infrared Lamp	Infrared Lamp	Same
Product Code	OAP	OAP	Same
Class	II	II	Same

Elements of Comparison	Subject Device	Predicate Device	Verdict
Intended Use / Indications for Use	The LED Hair Regrowth(MZ-07) is indicated to treat Androgenetic Alopecia and to 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.	The REVIAN RED device is indicated to treat Androgenetic Alopecia and to 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
Location for use	OTC	OTC	Same
Intended User	Females & Males	Females & Males	Same
Type of light	Visible red light-emitting diodes	Visible red light-emitting diodes	Same
Wavelength	660 nm	620-660 nm	Similar Note1
Amount of diodes	120	119	Similar Note 2
Power Supply	lithium battery	lithium polymer	Same
Irradiance	1.67 mw/cm^2	Not available	Different Note 3
Fluence	1 J/cm^2	Not available	Different Note 3
Distribution	Uniform distribution	Uniform distribution	Same
Treatment Time	Every day 10 mins	Every day 10 mins	Same
Helmet/Cap design	Yes	Yes	Same
Safety	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-57, IEC 62471, IEC 62133-2	Complied with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 62471	Same
Biocompatibility	All patient contacting materials are complied with ISO 10993-5, ISO 10993-10	All patient contacting materials are comply with ISO 10993-5, ISO 10993-10	Same

Comparison in Detail(s):

Note 1:

Although the “Wavelength” of the subject device is slightly different from the predicate device, the wavelength of the subject device is included in the wavelength range of the predicate device. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 2:
Although the “Amount of diodes” of the subject device is slightly different from the predicate device, specifications between them is different and the overall fluence is similar. So, the slightly difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

Note 3:
Although there is no publicly available of the “irradiance” and the “fluence” for the predicate device, the subject device has the same / similar treatment parameters in “wavelength”, “amount of diodes”, “distribution” and “treatment time” with the predicate device. So, the difference between the subject device and the predicate device will not raise any safety or effectiveness issues.

8. Test Summary

7.1 Summary of Non-Clinical Performance Testing

1） Performance Testing Summary

The CurrentBody Skin™ Led Hair Regrowth (Model: MZ-07) has been evaluated the safety and performance by lab bench testing as following:

Title of the test	Device Description/Sample Size	Test Method/Applicable Standards	Acceptance criteria	Unexpected Results/ Significant Deviations	Test results
General requirements for basic safety and essential performance	The test sample is the final, finished product.	2005/(R)2012 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Electromagnetic disturbances	The test sample is the final, finished product.	IEC 60601-1-2:2020	No degradation of performance was found during test or Lower than limits of measurement.	NA	Pass
Requirements for medical electrical equipment and medical electrical systems used	The test sample is the final, finished product.	IEC 60601-1-11: 2020	The device operates normally, and can provide basic safety and essential performance.	NA	Pass

in the home healthcare environment					
Particular Requirements for The Basic Safety And Essential Performance Of Non-Laser Light Source Equipment Intended For Therapeutic, Diagnostic, Monitoring And Cosmetic/Aesthetic Use	The test sample is the final, finished product.	IEC 60601-2-57:2011	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass
Photobiological safety of lamps and lamp systems.	The test sample is the final, finished product.	IEC 62471:2006	The test is carried out under the test method specified in the standard, and the test result is within the test acceptance range of the standard.	NA	Pass

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)
Shell (Outer surfaces)	PC+ABS	Surface-contacting device: skin	≤30 mins
Shell (Inner surface)	Silicone	Surface-contacting device: skin	≤30 mins

The Nature of body contact is scalp, 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 component materials for Shell (Outer surfaces and inner surface) of the CurrentBody Skin™ Led Hair Regrowth (Models: MZ-07) is identical to the corresponding component for Shell (Outer surfaces and inner surface) of the LED Eye Perfector (Model: EY-36A) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents), that manufactured by Light Tree Ventures Europe B.V. and has been cleared in K221444 on December 08, 2022.

3) Usability Testing

Usability testing was conducted on the CurrentBody Skin™ Led Hair Regrowth (Model: MZ-07), the device complies with IEC 62366-1 and IEC 60601-1-6.

4) 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.

5) 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 devices K173729.