December 24, 2025

Light Tree Ventures Europe B.V.
Kim Markwat
CEO
Laan van Ypenburg 108
Den Haag, 2497 GC
Netherlands

Re: K253349
Trade/Device Name: Hair Regrowth Cap (Model: T-119-HRC)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: August 22, 2025
Received: September 30, 2025

Dear Kim Markwat:

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: 2025.12.24 00:10:35 -05'00'

Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K253349

Device Name
Hair Regrowth Cap (Model: T-119-HRC)

Indications for Use *(Describe)*
Hair Regrowth Cap 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.

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) #: K253349

510(k) Summary

Prepared on: 2025-12-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Light Tree Ventures Europe B.V.
Applicant Address	Laan van Ypenburg 108 Den Haag 2497 GC Netherlands
Applicant Contact Telephone	+31629179372
Applicant Contact	Mr. Kim Markwat
Applicant Contact Email	Regulatory@lighttreeventures.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Hair Regrowth Cap (T-119-HRC)
Common Name	Infrared lamp
Classification Name	Laser, Comb, Hair
Regulation Number	890.5500
Product Code(s)	OAP

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K173729	Revian Red	OAP

Device Description Summary

21 CFR 807.92(a)(4)

The Hair Regrowth Cap (HRC) is a wearable device designed to treat androgenetic alopecia in both men and women. The cap utilizes LED light phototherapy to stimulate hair regrowth through a daily treatment session of approximately 10 minutes.
The system consists of a soft, comfortable textile cap embedded with LEDs, powered by a rechargeable battery. It includes driver electronics and is easily operated via a built-in switch button located on the cap. Hair Regrowth Cap device cannot operate while charging. The device has no communication function.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

Hair Regrowth Cap 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.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use are the same.

Technological Comparison

21 CFR 807.92(a)(6)

Hair Regrowth Cap has same technological characteristics as the Revian Red device (K173729), including intended use, wavelengths of emission (655+/-5nm), treatment time (10 minutes) and light energy delivery method (LED). The wavelength off the subject device (655 +/-5nm) and the measured irradiance of the subject device (18.4 mW/cm2) is similar to the wavelength (620-660nm) and the measured

irradiance (19.1 mW/cm2 from both 655nm and 620nm) of the predicate device.
The differences between subject device and predicate device do not raise and new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

1.Safety and Performance Test
The Hair Regrowth Cap device has been evaluated for its safety and performance by lab bench testing as following:
1.IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV Medical electrical equipment - Part 1. General requirements for basic safety and essential performance
2). IEC 60601-1 -2:2014/AMD1:2020 Amendment 1 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
3). IEC 60601-1-11:2015/AMD1:2020 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
4). IEC 60601-2-57:2023 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, cosmetic and aesthetic use
5). IEC 62471:2006 Photo biological safety of lamps and lamp systems All the test has been passed.

2.Software verification and validation testing
Software verification and validation testing were conducted and basic level of documentation was provided as recommended by FDA's Guidance "Content of Premdrket Submissions for Device Softwdre Functions (2023)".

3.Cybersecurity
The subject device no any external interfaces, no need cybersecurity evaluation.

4. The biocompatibility evaluation for the body-contacting components of the device was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process'", Document Issued on September 4, 2020, as recommended by FDA:
a. ISO 10993-5: 2009, Biological evaluation of medical devices –Par t 5: Tests for in vitro cytotoxicity
b. ISO 10993-10: 2021, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
c. ISO 10993-23: 2021, Biological evaluation of medical devices - Part 23: Tests for irritation

5. Clinical Performance
Clinical testing was not needed for this 51 0(k). The non-clinical performance testing described above is sufficient to support that the device can be used safely and effectively.

Based on the above analysis and non-clinical tests performed, it can be concluded that the subject device is as safe, as effective, and performs as well as the legally marketed predicated device.