April 28, 2023

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

Re: K230597
Trade/Device Name: Aduro Comb (Model SZ-22A)
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP
Dated: March 2, 2023
Received: March 3, 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,

Jianting Wang -S

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)*
K230597

Device Name
Aduro Comb (Model: SZ-22A)

Indications for Use *(Describe)*
The Aduro Comb (Model: SZ-22A) 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) Summary of K230579

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

1. Submitter's Information

Sponsor Name: Light Tree Ventures Europe B.V.
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Application Correspondent

Contact Person: Alain Dijkstra
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Manufacture

Company Name: Shenzhen Kaiyan Medical Equipment Co., Ltd
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Summary Prepared Date: 2023-04-03

2. Subject Device Information

Trade Name: Aduro Comb, model: SZ-22A
Classification Name: Laser, Comb, Hair (OAP)
Review Panel: Plastic Surgery
Product Code: OAP
Regulation Number: 21 CFR 890.5500
Regulation Class: II

3. Predicate Device Information

Predicate Device (K211038)

Sponsor: Biophotas Inc
Trade Name: Biophotas Celluma RESTORE
Classification Name: Laser, Comb, Hair
510(k) Number: K211038
Review Panel: General & Plastic Surgery
Product Code: OAP

Regulation Number: 21 CFR 890.5500
Regulation Class: II

4. Device Description

The Aduro Comb is (Model: SZ-22A) a comb-shaped device that emits led light with the intention to promote hair growth. The device provides distributed led to the scalp at 650nm (±10nm) while the comb teeth simultaneously part the user's hair to ensure the light reaches the user's scalp. The device is designed as a handheld product, and it consists of the main unit, the charging dock and a power cable, as well as it is powered by the built-in rechargeable lithium battery. The device has only one key for switching on and off the device and it will automatically shut down after a 10-minute treatment is completed.

5. Intended Use / Indications for Use

The Aduro Comb (Model: SZ-22A) 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.

6. Comparison to Predicate Device

Compared with the predicate device, the subject device has similar in the design principle, the intended use, the indications for use, functions and applicable standards. The differences between the subject device and the predicate device do not raise any new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Remark
Company	Light Tree Ventures Europe B.V.	Biophotas Inc	--
Trade Name	Aduro Comb (Model: SZ-22A)	Biophotas Celluma RESTORE	--
Classification Name	Laser, Comb, Hair (OAP)	Laser, Comb, Hair (OAP)	--
510(k) Number	K230579	K211038	--
Product Code	OAP	OAP	Same
Intended Use / Indications for Use	The Aduro Comb (Model: SZ-22A) 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	The BioPhotas Celluma RESTORE 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	Same

Elements of Comparison	Subject Device	Predicate Device	Remark
	Types I - IV.	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.	
Wavelengths	650±10nm	640nm (±25nm)	Similar Note 1
Treatment time	Each Treatment: 30 min Total Treatment: every other day, for 16 weeks	Each Treatment:30 min Total Treatment: every other day, for 16 weeks	Same
Treatment area	31.5 cm^2	475 cm^2	Different Note 2
Energy density (mw/cm^2)	2.77 mw/cm^2	2.77 mw/ cm^2	Same
Treatment Dose(J/cm^2)	4.98 J/ cm^2	4.98 J/ cm^2	Same
Energy Source	Light emitting diodes	Light emitting diodes	Same
Number of LEDs	22 LEDs	No publicly available	Different Note 2
Power supply	Input: 100-240V~, 50/60Hz, 0.35Amax Output:5V, 2A Battery: DC 3.7 V, 600 mAh, 2.22 Wh	110-120V	Similar Note 3
Location for Use	OTC	OTC	Same
Safety and EMC	IEC 60601-1 IEC 60601-1-11 IEC 62471 IEC 60601-2-57 IEC 60601-1-2 IEC 62133-2	IEC 60601-1 IEC 60601-1-2	Similar Note 4
Biocompatibility	All patient contacting materials comply with ISO 10993-5, ISO 10993-10	All patient contacting materials comply with ISO 10993-5, ISO 10993-10	Same

Note 1: Although the “Wavelength” of the subject device has a slight difference from the predicate devices, the wavelength of the subject device is within the error range of the predicate devices, so the wavelength of the subject device can be fully covered by the predicate devices. Therefore, this difference between the subject device and predicate devices will not raise any safety or effectiveness issues.

Note 2: Although the “Treatment area” and the “Number of LEDs” are different from the predicate devices because of the different design shapes, both the subject device and predicate devices have the same treatment parameters. Therefore, these slight differences between the subject device and predicate devices will not raise any safety or effectiveness issues.

Note 3: Although the “Power supply” of the subject device is not exactly the same as the predicate devices, both the subject device and the predicate devices conduct the safety test according to the IEC 60601 series standards, and the test results are in compliance with safety standards’ requirements. So, this difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

Note 4: Although the description in “Safety and EMC” of the subject device is slightly different from the predicate devices, both the subject device and the predicate devices conducted the electrical safety and electromagnetic compatibility tests according to the international series standards, and the test results are in compliance with the standards’ requirements. So, this difference between the subject device and the predicate devices will not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- AAMI/ANSI ES60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2 (2021)
- 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
- 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
- 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
- IEC 62471 Photobiological safety of lamps and lamp systems
- 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

2) Biocompatibility

The component materials of the subject device are identical to the corresponding component materials of the e previously cleared devices (K203271 and K202390) in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

There is no change in biocompatibility since the previously cleared devices. Therefore, based on this information, the subject device can comply with the biocompatibility requirements of ISO 10993-5 (Cytotoxicity), ISO 10993-10 (Sensitization), and ISO 10993-10 (Irritation).

3) Software verification and validation testing

Software verification and validation testing were conducted and documentation was provided as recommended by the IEC 62304 and 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.

7.2 Summary of 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.

Final Conclusion:

The subject device is as safe, as effective, and performs as well as or better than the legally marketed predicated devices K211038.