May 12, 2026

Light Tree Ventures Europe B.V.
Alain Dijkstra
Manager
Unit 2.01 Saturnusstraat 95
Den Haag, 2516AG
Netherlands

Re: K260415
Trade/Device Name: myLEDmask 2 (MJ-144)
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: OHS
Dated: January 26, 2026
Received: February 9, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.05.12 19:23:34 -04'00'

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)*
K260415

Device Name
myLEDmask 2 (MJ-144)

Indications for Use *(Describe)*
myLEDmask 2 (MJ-144) is an over-the-counter device designed to emit energy in the visible and infrared spectrum intended for use in the treatment of full-face wrinkles.

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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510(k) Summary of K260415

This summary of 510(k) 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.
Establishment Registration Number: 3017422691
Address: Unit 2.01 Saturnusstraat 95, 2516 AG Den Haag, The Netherlands
Contact Person (including title): Kim Markwat(CEO)
E-mail: kim@lighttreeventures.com

Manufacturer:

Company Name: Light Tree Ventures Europe B.V.
Establishment Registration Number: 3017422691
Address: Unit 2.01 Saturnusstraat 95, 2516 AG Den Haag, The Netherlands
Contact Person (including title): Kim Markwat (CEO)
Email: kim@lighttreeventures.com

Distributor:

Company Name: myBlend (Clarins Group)
Address: 9 RUE DU COMMANDANT PILOT, 92200 NEUILLY-SUR-SEINE, FRANCE

Application Correspondent:

Company: Light Tree Ventures Europe B.V.
Address: Unit 2.01 Saturnusstraat 95, 2516 AG Den Haag, The Netherlands
Email: registrar01@kaiyanmedical.com

2. Subject Device Information:

Device/Trade Name: myLEDmask 2 (MJ-144)
Classification Name: Light Based Over the Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number:21 CFR 878.4810
Regulation Class: II

3. Predicate Device Information

Predicate Device 1 (K223147)

Sponsor: MyBlend
Trade Name: myLEDmask
Classification Name: Light Based Over the Counter Wrinkle Reduction
Review Panel: General & Plastic Surgery
Product Code: OHS
Regulation Number: 21 CFR 878.4810
Regulation Class: II

4. Device Description

MyLEDmask 2 (MJ-144) is a device that uses light-emitting diode (LED) technology on the face. Light is emitted from the inner surface of the device onto the face. This light is generated by LEDs with two different spectrum wavelengths: red (630nm) and near-infrared (850nm). Three Care programs (LEDs activation duration) based on 3 skin phototypes (skin tone) are available.

- Program 1 Fair Skin
- Program 2 Moderately Dark Skin
- Program 3 Dark Skin

The device is operated by a controller and powered by rechargeable batteries. The controller features a digital display that shows the battery level, selected treatment program and treatment countdown timer. To protect the eyes from LED exposure during use, myLEDmask 2 equips with protective eyeshield that blocks light energy from the LEDs. At the end of each treatment session, the device will automatically switch off.

5. Intended Use / Indications for Use

myLEDmask 2 (MJ-144) is an over-the-counter device designed to emit energy in the visible and infrared spectrum intended for use in the treatment of full-face wrinkles.

6. Comparison to Predicate Devices

Compare with the predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards.

Elements of Comparison	Subject Device	Predicate Device (K223147)	Remark
Company	Light Tree Ventures Europe B.V.	MyBlend	--
510 (K) Number	Applying	K223147	--
Device Name	myLEDmask 2	myLEDmask	--
Model	MJ-144	/	--
OTC/Rx	OTC	OTC	Same
Device Classification	Class II	Class II	Same
Product Code	OHS	OHS	Same
Regulation Number	21 CFR 878.4810	21 CFR 878.4810	Same
Indications for Use / Intended use	myLEDmask 2 (MJ-144) is an over-the-counter device designed to emit energy in the visible and infrared spectrum intended use in the treatment of full-face wrinkles.	myLEDmask is an over-the-counter device that is intended to emit energy in the visible and infrared region of the spectrum for use in the treatment of full-face wrinkles.	Same
Intended Area of Use	Face	Face	Same

Elements of Comparison	Subject Device	Predicate Device (K223147)	Remark
Power Source	Rechargeable Lithium battery	Rechargeable Lithium battery	Same (Note 1)
Energy Type	Light emitting diodes	Light emitting diodes	Same
Type	Mask	Mask	Same
LED Wavelength	Red: 630nm±5nm Infrared: 850nm ±5nm	Red: 630 nm NIR: 850 nm	Same
LED Number	Total 288 LEDs - 144 for 630 nm and 144 for 850 nm - 240 for the face and 48 for the neck	Total 288 LEDs - 144 for 630 nm and 144 for 850 nm - 244 for the face and 44 for the neck	Similar (Note 2)
Total Intensity (mW/cm^2)	Total: 12-24 mW/cm^2 Red: 8-16mW/CM^2 Infrared: 4-8mW/CM^2	18.7 mW/cm^2 (average of 6 measurement location (including one on the neck) between 10 to 27 mW/cm^2)	Similar (Note 2)
Treatment Time	According to skin phototype, - Program 1 fair skin: 5 min 30 - Program 2 moderately dark skin: 11min - Program 3 dark skin: 14 min during 8 weeks	According to skin phototype, daily - 1 fair skin: 5 min 35 (335 s) - 2 moderately dark skin: 11min 10 (670 s) - 3 dark skin: 13 min 55 (835 s) during 6 to 8 weeks	Similar (Note 2)
Software controller	Device uses a timer and software to control treatment duration	Device uses a timer and software to control treatment duration	Same
Electrical Safety	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-83 IEC 62471	Compliant with IEC 60601- 1, IEC 60601-1-2, IEC 60601-2-57	Same
Biocompatibility	ISO 10993-1 ISO10993-5 ISO10993-10 ISO10993-23	ISO 10993-1 ISO10993-5 ISO10993-10 ISO10993-23	Same

Comparison in Detail(s):

Note 1:

The power supply design of the subject device is similar to that of the predicate device. Furthermore, its

lithium battery has been tested in compliance with the IEC 62133-2 standard. Therefore, this minor difference does not pose any safety concerns.

Note 2:
The LED number, output intensity and treatment duration of the subject device differ only slightly from those of the predicate device. The values are very close and remain within the tolerance range of the predicate device. Additionally, the subject device complies with the safety requirements of IEC60601-1, IEC60601-1-2, IEC60601-2-83, and IEC62471 standards. Therefore, these minor differences do not raise any safety or effectiveness issues.

7. Test Summary

7.1 Non-Clinical Tests Performed

1) Electrical safety, and electromagnetic compatibility Test

Non-clinical testing was performed on the subject device to validate the design and ensure compliance with the following standards related to medical device electrical safety, electromagnetic compatibility, photobiological safety and battery safety:

- IEC 60601-1 2020-08 Edition 3.2 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2015+AMD1:2020 Edition 2.1 Medical Electrical Equipment - Part 1: 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 60601-2-83:2019+AMD1:2022 Edition 1.1 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment
- IEC 60601-1-2 Edition 4.1 2020-09 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC TS 60601-4-2:2024 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems
- IEC 62471 First edition 2006-07 Photobiological safety of lamps and lamp systems.
- IEC 62133-2:2017+AMD1:2021 Edition1.1 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 Test

The components of myLEDmask 2 (Model: MJ-144) conform to ISO 10993-5:2009 - Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity, ISO 10993-10:2021 - Biological evaluation of medical devices - Part 10: Tests for skin sensitization and ISO 10993-23:2021 - Biological evaluation of medical devices - Part 10: Tests for irritation.

3) Software Verification and Validation

Software verification and validation testing were conducted in accordance with the recommendations provided in the FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The corresponding Basic documentation has been provided.

4) Usability Validation

Usability testing was conducted on the myLEDmask 2 (MJ-144).

7.2 Summary of Clinical Performance

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

8. Date Prepared: May 11, 2026

9. Final Conclusion

The subject device is equally safe, effective, and performs as well as the legally marketed predicate device K223147.