September 23, 2025

Luminance Medical Ventures, Inc.
% Nathan Glass
RAQA Consultant
MedLaunch, LLC
17437 Carey Rd
#102
Westfield, Indiana 46074

Re: K251973
Trade/Device Name: Luminance Red Cold Sore Device (TN1927G)
Regulation Number: 21 CFR 878.4860
Regulation Name: Light Based Energy Source Device For Topical Application
Regulatory Class: Class II
Product Code: OKJ
Dated: June 20, 2025
Received: June 26, 2025

Dear Nathan Glass:

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: 2025.09.23 14:09:44 -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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251973

Please provide the device trade name(s).

Luminance Red Cold Sore Device (TN1927G)

Please provide your Indications for Use below.

The Luminance Red Cold Sore device is indicated for shortening the time to healing of herpes simplex labialis lesions on and around the lips with time to healing defined as the time to patient described re-epithelialization.

This device is suitable for users with Fitzpatrick skin types I-IV.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) #: K251973

510(k) Summary

Prepared on: 2025-09-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Luminance Medical Ventures, Inc.
Applicant Address	2310 Henderson Avenue #1297 Dallas TX 75201 United States
Applicant Contact Telephone	214-206-5057
Applicant Contact	Mr. Troy Stites
Applicant Contact Email	troy@luminancemedical.com
Correspondent Name	MedLaunch, LLC
Correspondent Address	17437 Carey Rd #102 Westfield IN 46074 United States
Correspondent Contact Telephone	317-643-2372
Correspondent Contact	Mr. Nathan Glass
Correspondent Contact Email	nglass@medlaunch.tech

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Luminance Red Cold Sore Device (TN1927G)
Common Name	Light Based Treatment For Cold Sores Herpes Simplex Virus-1
Classification Name	Light based energy source device for topical application
Regulation Number	878.4860
Product Code(s)	OKJ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K222205	Light Tree Ventures, Cold Sore Device	OKJ

Device Description Summary

21 CFR 807.92(a)(4)

The Luminance Red Cold Sore Device is a lightweight, handheld device that consists of a body handle and treatment head. The body handle contains LEDs that emit non-therapeutic visible red light and therapeutic invisible near-infrared light (1072 nm +/ 12 nm) through the treatment head. The non-therapeutic visible red light serves as a guidelight and is intended to enhance the usability of the device. The body consists of a plastic shell, which includes a button to turn the device on, a button to start treatment, and a digital countdown timer. The Luminance Red Cold Sore Device is powered by a lithium-ion battery.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Luminance Red Cold Sore device is indicated for shortening the time to healing of herpes simplex labialis lesions on and around the lips with time to healing defined as the time to patient described re-epithelialization.

This device is suitable for users with Fitzpatrick skin types I-IV.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use are the same for the subject device as compared to the predicate device.

Technological Comparison 21 CFR 807.92(a)(6)

A comparison of technological characteristics was completed between the subject and predicate devices. There are minor differences in the materials of manufacture and battery, as well as the inclusion of a non-therapeutic visible red light. The materials of the subject device have been assessed to confirm that there are no biological safety concerns for the intended use and duration of contact. The battery capacity has been increased in order to allow for more use between charges. Battery testing was completed. The non-therapeutic visible red light serves as a guidelight and is intended to enhance the usability of the device, and inclusion of this guidelight does not raise any new questions of safety or effectiveness.

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

Electromagnetic Compatibility and Electrical Safety
- IEC 62471 First edition 2006-07, Photobiological safety of lamps and lamp systems
- IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012
- IEC 60601-1-2 Edition 4.0 2014-02, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-11 Edition 2.0 2015-01, 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 Edition 1.0 2011-01, 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

Software Verification and Validation
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION, Medical device software - Software life cycle processes

Biocompatibility
- ISO 10993-1 Fifth edition 2018-08, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- ISO 10993-5 Third edition 2009-06-01, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Edition 4 2021-11, Biological evaluation of medical devices - Part 10: Tests for skin sensitization
-SO 10993- 23 Edition 1 2021-01, Biological evaluation of medical devices - Part 23: Tests for skin irritation

Usability
- Applying Human Factors and Usability Engineering to Medical Devices Guidance for Industry and Food and Drug Administration Staff
- IEC 62366-1 Edition 1.0 2015-02, Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]

No clinical testing was conducted for the Luminance RED Cold Sore device.

Verification and validation testing was conducted and the Luminance RED Cold Sore Device according to appropriate standards and requirements, with all tests passing associated acceptance criteria. Luminance believes that the Cold Sore Device presents no undue risk to the patient or physician as outlined in this report while offering, at minimum, comparable benefits to other systems in use today. When used in accordance with the indications for use, the Cold Sore Device is an acceptably low risk. The overall benefits of these devices outweigh the potential risks. Given this, the subject device has been demonstrated to be substantially equivalent to the predicate device K222205.