November 4, 2024

LumiThera, Inc.
Lori Holder
VP, Regulatory Affairs
19578 10th Ave. NE
Ste 200
Poulsbo, WA 98370

Re: DEN230083
Trade/Device Name: Valeda Light Delivery System
Regulation Number: 21 CFR 886.5520
Regulation Name: Light based device for dry age-related macular degeneration
Regulatory Class: Class II
Product Code: SDE
Dated: December 13, 2023
Received: December 14, 2023

Dear Lori Holder:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Valeda Light Delivery System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Valeda Light Delivery System is intended to provide improved visual acuity in patients with best-corrected visual acuity of 20/32 through 20/70 and who have dry age-related macular degeneration (AMD) characterized by:
>
> - The presence of at least 3 medium drusen (> 63 μm and ≤ 125 μm in diameter), or large drusen (> 125 μm in diameter), or non-central geographic atrophy, AND
> - The absence of neovascular maculopathy or center-involving geographic atrophy.
>
> After about two years, the Valeda Light Delivery System treatment provides improved mean visual acuity of approximately one line of visual acuity (ETDRS) compared to those not receiving the treatment.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Valeda Light Delivery System, and substantially equivalent devices of this generic type, into Class II under the generic name Light based device for dry age-related macular degeneration.

FDA identifies this generic type of device as:

> **Light based device for dry age-related macular degeneration**. A light based device for dry age-related macular degeneration is a prescription device intended for use in the application of non-coherent light energy to the eye. The device treats or improves visual acuity in patients with dry age-related macular degeneration

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act.
On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On December 14, 2023, FDA received your De Novo requesting classification of the Valeda Light Delivery System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Valeda Light Delivery System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the Valeda Light Delivery System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type.

The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Method
Ineffective treatment leading to worsening of condition	Clinical performance data Non-clinical performance testing Labeling
Therapeutic effect not sustained leading to delay of treatment and worsening of vision or progression of disease	Clinical performance data Non-clinical performance testing Labeling
Failure of software or system components leading to ineffective treatment or ocular adverse events	Clinical performance data Non-clinical performance testing Software verification, validation, and hazard analysis Labeling
Ocular light hazard	Clinical performance data Non-clinical performance testing
Equipment malfunction leading to user or patient injury (e.g., shock, burn, interference)	Electromagnetic compatibility (EMC) testing Electrical safety testing Labeling
Adverse tissue reaction	Biocompatibility evaluation

In combination with the general controls of the FD&C Act, the Light based device for dry age-related macular degeneration is subject to the following special controls:

1. Clinical performance data must demonstrate that the device or representative test device performs as intended under anticipated conditions of use. Data must include:

   (i) Adverse events, including all ocular and periorbital events;
   (ii) Assessment of ocular and retinal tissue damage;
   (iii) Assessment of best corrected visual acuity; and
   (iv) Assessment of progression to neovascular age-related macular degeneration and to geographic atrophy.

2. Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:

   (i) Optical radiation safety evaluation (including a description of the optical path and light sources); and
   (ii) Testing to demonstrate that the device maintains optical output specifications within all intended environmental operating conditions.

3. Software verification, validation, and hazard analysis must be performed. Documentation must include characterizations of the technical specifications of the software including a description of interactions between software and hardware; specifically, a controlling and monitoring of treatment related hardware.

4. Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device in the intended use environment.

5. Patient-contacting components of the device must be demonstrated to be biocompatible.

6. Labeling must include:

    (i) Device treatment procedure and parameters for each treatment session supported by clinical performance data;
    (ii) The frequancey and length of treatment regimen supported by clinical performance testing; and
    (iii) A summary of the clinical performance data obtained with the device or representative test device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the Light based device for dry age-related macular degeneration they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD & C 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 FD & C Act); 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.
As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Shulei Zhao at 240-402-5358.

Sincerely,

Denise L. Hampton -S

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health