August 21, 2026

MATAP II LLC
David Pudwill
Regulatory Consultant
Mr. Regulatory
1033 Vinsetta Circle
Winter Garden, Florida 34787

Re: DEN250026
Trade/Device Name: Avulux
Regulation Number: 21 CFR 882.5811
Regulation Name: Light Attenuation Lenses for Migraine-associated Light Sensitivity
Regulatory Class: Class I
Product Code: QEO
Dated: June 20, 2025
Received: June 23, 2025

Dear David Pudwill:

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 Avulux, an over-the-counter device under 21 CFR Part 801 Subpart C with the following indications for use:

> Avulux is a precision optical filter indicated to block light at 480 nm (high blue range) and 590 nm (red/amber range), while allowing light in the remaining visible color spectrum through, to decrease the impact of light sensitivity in patients diagnosed with episodic migraine aged 12 years of age and older. The use of the Avulux should not alter the usual care therapy of patients diagnosed with episodic migraine, including medication usage

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 I. This order, therefore, classifies the Avulux, and substantially equivalent devices of this generic type, into Class I under the generic name Light Attenuation Lenses for Migraine-associated Light Sensitivity.

FDA identifies this generic type of device as:

> **Light attenuation lenses for migraine-associated light sensitivity**. Light attenuation lenses for migraine-associated light sensitivity are devices that limit light incidence of specific wavelengths to the eyes and are intended to decrease the impact of light sensitivity in patients diagnosed with migraine. The lenses can be mounted on a spectacle frame, clips, or other apertures used to hold

lenses. The device is intended to be adjunctive to other therapies for migraine-associated light sensitivity. Sunglasses (nonprescription) and prescription spectacle lenses are separately classified under § 886.5850 and § 886.5844, respectively.

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 June 23, 2025, FDA received your De Novo requesting classification of the Avulux. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Avulux 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 Avulux can be classified in class I. FDA believes that class I (general) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks to health are eye injuries resulting from the shattering of lenses, delayed response to time-sensitive color-based signals, and failure to seek medical attention from other causes of symptoms associated with migraine.

The Light Attenuation Lenses for Migraine-associated Light Sensitivity is subject to the general controls of the FD&C Act. Section 510(l) of the FD&C Act (21 U.S.C. 360(l)) provides that a class I device is not subject to the premarket notification requirements under section 510(k) of the FD&C Act unless the device is of substantial importance in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. FDA has determined that the device does not meet these criteria and, therefore, premarket notification is not required for the device. Thus, persons who intend to market this device need not submit a premarket notification containing information on the Avulux they intend to market prior to marketing the device, subject to the limitations on exemptions in 882.9.

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 Management System Regulation (QMSR) (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 Beomseo Koo, PhD at 301-796-0855.

Sincerely,

JAY R. GUPTA -S

Jay Gupta
Director
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
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