May 15, 2024

Notal Vision, Inc.
c/o Lee Kramm M.D., M.S.E.
President, Chief Strategist and Medical Officer
Regulatory Pathways Group, Inc.
440 N. Barranca Ave #2471
Covina, California 91723

Re: DEN230043
Trade/Device Name: Notal Vision Home Optical Coherence Tomography (OCT) System
Regulation Number: 21 CFR 886.1600
Regulation Name: Home monitoring ophthalmic imaging device
Regulatory Class: Class II
Product Code: SAX
Dated: June 7, 2023
Received: June 7, 2023

Dear Dr. Kramm:

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 Notal Vision Home Optical Coherence Tomography (OCT) System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The Notal Vision Home Optical Coherence Tomography (OCT) System is an Artificial Intelligence (AI)-based Home Use device indicated for visualization of intraretinal and subretinal hypo-reflective spaces in a 10 by 10-degrees area centered on the point of fixation of eyes diagnosed with neovascular age-related macular degeneration (NV-AMD). In addition, it provides segmentation and an estimation of the volume of hypo-reflective spaces. The Notal Home OCT device is intended for imaging at home between regularly scheduled clinic assessments and not intended to be used to make treatment decisions or replace standard-of care regularly scheduled examinations and clinical testing as needed, including in-office imaging and assessments for changes in vision, by an ophthalmologist.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Notal Vision Home Optical Coherence Tomography (OCT) System, and substantially equivalent devices of this generic type, into Class II under the generic name home monitoring ophthalmic imaging device.

FDA identifies this generic type of device as:

> **Home monitoring ophthalmic imaging device**. A home monitoring ophthalmic imaging device is a prescription self-imaging device that incorporates imaging system hardware and automated image processing and analysis to enable patients at home to provide measurements that are intended for use

by a physician for monitoring ophthalmic diseases or conditions in between regularly scheduled assessments.

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 7, 2023, FDA received your De Novo requesting classification of the Notal Vision Home Optical Coherence Tomography (OCT) System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Notal Vision Home Optical Coherence Tomography (OCT) 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 and interactively via email, FDA has determined that, for the previously stated indications for use, the Notal Vision Home Optical Coherence Tomography (OCT) 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 Measures**
Inaccurate results related to false negative findings, leading to missed clinician alerts and delayed disease management	Clinical performance testing Non-clinical performance testing Software description, verification, validation and hazard analysis Human factors validation testing Labeling
Inaccurate results related to false positive findings, leading to unnecessary medical procedures	Clinical performance testing Non-clinical performance testing Software description, verification, validation and hazard analysis Human factors validation testing Labeling
Operator failure to self-image and obtain images that meet input quality specifications, resulting in failure to monitor disease progression	Training Human factors validation testing Labeling

Risks to Health	Mitigation Measures
Ocular light toxicity	Non-clinical performance testing
Equipment malfunction leading to user 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 home monitoring ophthalmic imaging device is subject to the following special controls:

(1) Clinical performance testing must demonstrate that the device performs as intended for the stated indications for use under anticipated conditions of use. Testing must:
  (i) Evaluate accuracy of measurements and image annotations;
  (ii) Evaluate the variability in output performance due to the end user and the device used; and
  (iii) Evaluate the device at clinical sites that are independent of the sites used to train the software.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Testing must include:
  (i) Verification of image quality, field of view, and resolution; and
  (ii) Optical radiation safety evaluation (including a description of the optical path and light sources).

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

(4) Software verification, validation and hazard analysis must be performed. Software documentation must include the following:
  (i) A description of interactions between software and hardware;
  (ii) A description of all inputs and outputs of the algorithm(s);
  (iii) A description of software modules that score, label, detect, quantitate, characterize, or otherwise analyze and report results, both separately and as a total system;
  (iv) A description of the data used to train and test software modules, including number of cases, sources (sites and data acquisition devices), demographics, and reference standard;
  (v) A description of the expected impact of applicable image acquisition hardware characteristics on performance and associated minimum specifications; and
  (vi) Mitigation measures to manage failure of any subsystem components with respect to incorrect patient reports and operator failures.

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

(6) A training program must be included with sufficient educational elements so that upon completion of the training program, the user can operate the device in the indicated environment of use.

(7) Human factors testing must demonstrate that the intended users can correctly use the device.

(8) Labeling must include:
  (i) Instructions for home use, including instructions on how the home user obtains quality self-images, and an explanation of how the device performance is affected by user interaction;
  (ii) Physician instructions for use, including a description of the outputs and all user-interface components;

(iii) Warnings regarding image acquisition factors that affect image quality;
(iv) A warning that the device should not be used to replace or delay in-office assessment; and
(v) A summary of the clinical performance testing conducted with the device, including a description of the patient population and environment in which it was evaluated.

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

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.

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 home monitoring ophthalmic imaging device 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).

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 Michelle Sandrian at 240-402-4866.

Sincerely,

Denise L. Hampton -S

for Malvina 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