August 6, 2024

Gary Mocnik, Regulatory Consultant
Balance Ophthalmics, Inc.
3101 W 57th Street
Sioux Falls, SD 51708

Re: DEN230055
Trade/Device Name: FSYX™ Ocular Pressure Adjusting Pump System
Regulation Number: 21 CFR 886.5000
Regulation Name: External ocular negative pressure system
Regulatory Class: Class II
Product Code: QQJ
Dated: August 25, 2023
Received: August 25, 2023

Dear Gary Mocnik:

This letter corrects our previous classification order, dated June 27, 2024, to correct your contact information.

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 FSYX™ Ocular Pressure Adjusting Pump System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The FSYX™ Ocular Pressure Adjusting Pump is indicated for the reduction of Intraocular Pressure (IOP) during sleep in adult patients with open-angle glaucoma and IOP ≤ 21 mmHg who are currently using or have undergone another IOP-lowering treatment.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the FSYX™ Ocular Pressure Adjusting Pump System, and substantially equivalent devices of this generic type, into Class II under the generic name external ocular negative pressure system.

FDA identifies this generic type of device as:

> External ocular negative pressure system. An external ocular negative pressure system uses hardware and software to create negative pressure in front of the eye to temporarily lower intraocular pressure in glaucoma patients.

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 August 25, 2023, FDA received your De Novo requesting classification of the FSYX™ Ocular Pressure Adjusting Pump System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the FSYX™ Ocular Pressure Adjusting Pump 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 FSYX™ Ocular Pressure Adjusting Pump 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 to health are shown in the table below. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	**Mitigation Measures**
Adverse tissue reaction	Biocompatibility evaluation
Excessive or insufficient negative pressure application and treatment duration leading to insufficient treatment of glaucoma and ocular and periorbital adverse events	Clinical performance testing Postmarket surveillance Non-clinical performance testing Labeling
Failure of software or system components resulting in insufficient treatment of glaucoma	Non-clinical performance testing Shelf-life testing Software verification, validation, and hazard analysis
User error leading to ocular and/or periorbital adverse events or insufficient treatment of glaucoma	Human factors validation testing Labeling
Inaccurate dosing due to lack of goggle seal resulting in insufficient treatment of glaucoma	Non-clinical performance testing
Equipment malfunction leading to user injury (e.g., shock, burn, interference)	Electromagnetic compatibility (EMC) testing Electrical safety testing Labeling

In combination with the general controls of the FD&C Act, the external ocular negative pressure system is subject to the following special controls:

(1) Data obtained from premarket clinical performance validation testing and postmarket surveillance acquired under anticipated conditions of use must demonstrate that the device performs as intended when used in the intended patient population, and must evaluate the following, unless FDA determines based on the totality of the information provided for premarket review that data from postmarket surveillance is not required:

(i) Adverse events, including all ocular and periorbital events, worsening of visual field and assessment of ocular tissue damage; and

(ii) Reduction in intraocular pressure while the device is in use.

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

(i) Verification and validation of critical system components, such as pressure generator, pressure delivery system, and power source; and

(ii) Evaluation of the fail-safe pressure release mechanism.

(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. Validation testing must verify and validate programmable treatment parameters. Software documentation must include the following:

(i) A description of programmable treatment limits such as negative pressure range and duration; and

(ii) Mitigation measures to manage failure of any software/firmware or subsystem components and operator failures relating to negative pressure output.

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

(6) Human factors testing must demonstrate that the intended users can correctly use the device, based solely on the device labeling.

(7) Labeling must include:

(i) Warnings regarding negative pressure and treatment duration limitations; and

(ii) A summary of the clinical performance testing conducted with the device, including a description of the study population, results, ocular and non-ocular adverse events.

In order to satisfy special control (1) above, FDA has determined that you must collect and report postmarket surveillance data acquired under anticipated conditions of use to demonstrate long-term safety when the device is used as intended. Specifically, you must conduct postmarket clinical validation performance testing of the FSYX Ocular Pressure Adjusting Pump System device in the intended patient population to evaluate long-term safety. This includes the collection of data from a fit-for-purpose patient-reported outcome measure (PROM) to evaluate the impact of the use of the device on certain aspects (e.g., sleep disturbance, headaches, ocular and periorbital pain) of health-related quality of life (HRQOL) in these patients.

FDA expects that the postmarket clinical validation performance testing will include a justified study sample size of FSYX Ocular Pressure Adjusting Pump System patients followed through 36 months. Post-operative follow-up will occur at 12, 24 and 36 months.

Within 30 days of receipt of the original classification order dated June 27, 2024, you must submit a complete study protocol for your study as described above. FDA expects to work with you to approve your study protocol within 60 days of this order. Your submission should be clearly labeled as a "De Novo Postmarket Study Protocol" and submitted to the Agency as specified below. Please reference the De Novo number above to facilitate processing. If there are multiple protocols being finalized after granting of this De Novo request, please submit each protocol as a separate submission, identified by their unique study name(s).

From the date of postmarket study protocol approval, you must meet the following timelines:

- First subject enrolled within 6 months
- 20% of subjects enrolled within 12 months
- 50% of subjects enrolled within 18 months
- 100% of subjects enrolled within 24 months

In addition, you must submit separate periodic reports on the progress of the new enrollment postmarket study as follows:

- Postmarket surveillance progress reports every six (6) months until subject enrollment has been completed, and annually thereafter, from the date of the protocol approval letter, unless otherwise specified by FDA.

- If any enrollment milestones are not met, you must begin submitting quarterly enrollment status reports every three (3) months in addition to your periodic postmarket surveillance progress reports, until enrollment has been completed or FDA notifies you otherwise.

- Submit the final postmarket surveillance report three (3) months from study completion (i.e., last subject's last follow-up date).

Each postmarket surveillance report should be submitted to the Agency as specified below, identified as a "De Novo Postmarket Surveillance Report" in accordance with how the study is identified above, and bearing the applicable De Novo reference number.

Be advised that failure to comply with any special control requirement, including the initiation, enrollment, completion, and reporting per the postmarket surveillance data requirements outlined above, may result in the adulteration and misbranding of your device.

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.

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 external ocular negative pressure system 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).

All required documents should be submitted, unless otherwise specified, to the address below and should reference the above De Novo number to facilitate processing.

De Novo Postmarket Surveillance
U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Alternatively, documents can be submitted electronically through the CDRH Portal. For more information on the CDRH Portal, please visit https://www.fda.gov/medical-devices/industry-medical-devices/send-and-track-medical-device-premarket-submissions-online-cdrh-portal.

If you have any questions concerning the contents of the letter, please contact Mira Sethi at 240-402-3175.

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