De Novo Classification Request for FSYX™ Ocular Pressure Adjusting Pump System

Regulatory Information

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.

New Regulation Number: 21 CFR 886.5000

Classification: II

Product Code: QQJ

Background

Device Name: FSYX™ Ocular Pressure Adjusting Pump System

Submission Number: DEN230055

Date De Novo Received: August 25, 2023

Sponsor Information:

Balance Ophthalmics
3101 W 57th Street
Sioux Falls, SD 51708 USA

Indications for Use

The FSYX Ocular Pressure Adjusting Pump System is indicated as follows:

> 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 $\leq$ 21 mmHg who are currently using or have undergone another IOP-lowering treatment.

Limitations

The sale, distribution, and use of FSYX™ Ocular Pressure Adjusting Pump System are restricted to prescription use in accordance with 21 CFR 801.109.

The following contraindications, warnings, and precautions apply to the FSYX™ Ocular Pressure Adjusting Pump System:

- Not for use in patients with allergy to silicone;
- Patients using the FSYX™ Ocular Pressure Adjusting Pump System should not modify or discontinue any of their other glaucoma treatments without consultation with their health care provider;
- Not recommended for use in patients with a history of retinal detachment or patients with narrow anterior chamber angle anatomy;
- The safety and effectiveness of the FSYX™ Ocular Pressure Adjusting Pump System has not been established in patients with the following conditions: penetrating keratoplasty, prior sub-conjunctival glaucoma surgery such as trabeculectomy and tube shunt;
- There is insufficient safety and effectiveness data for treatment durations > 6 hours and for negative pressure (NP) settings ≥ -17 mm Hg. Treatment durations between 6 and 8 hours and/or treatment at NP levels ≥ -17 mm Hg should be undertaken with caution. Treatment duration greater than 8 hours/session is not recommended.

PLEASE REFER TO THE LABELING FOR A COMPLETE LIST OF WARNINGS, PRECAUTIONS AND CONTRAINDICATIONS.

The device lowers IOP only while negative pressure is being properly applied. The effectiveness of the temporary IOP-lowering effect of the device to slow or halt glaucoma progression and to serve as a sole IOP-lowering treatment for glaucoma patients has not been established.

DEVICE DESCRIPTION

The FSYX™ Ocular Pressure Adjusting Pump System is comprised of two distinct elements, the programmable pump and the goggles with tubing. The FSYX™ Ocular Pressure Adjusting Pump System is designed to allow the application and monitoring of bilateral negative pressure (NP) in the microenvironment in front of a patient's eyes.

Figure 1A: FSYX Ocular Pressure Adjusting Pump; Figure 1B: FSYX Ocular Pressure Adjusting Pump System Goggles

The FSYX™ Ocular Pressure Adjusting Pump System goggles are designed to fit and seal around the eyes of patients, creating an air-tight chamber in which NP can be created and maintained. A headstrap is included with the goggles to facilitate reliable positioning on the patient's face during sleep. The goggles can be connected and disconnected from the FSYX™ Ocular Pressure Adjusting Pump to allow for daily cleaning. FSYX™ Ocular Pressure Adjusting Pump System goggles should be replaced every 30 days.

The FSYX™ Ocular Pressure Adjusting Pump houses 2 miniature diaphragm pumps that produce programmable NP pressure levels independently for each eye. The pumps are connected to a manifold that pneumatically interfaces the connector integral to the tubing system of the goggles. The manifold also mechanically and pneumatically connects a plurality of pressure sensors and relief valves. To create NP for each goggle lens, a pump extracts air from the cavity created by the goggle and the patient's face. The pump is pneumatically connected to the goggle through a negative pressure line comprised of a tube, a portion of the connector, and a portion of the manifold. The air extracted from the goggle is evacuated from the FSYX™ Ocular Pressure Adjusting Pump through a pneumatic path integral to the manifold. For each individual goggle, there is a separate pump and NP line, which allows independent NP application treatments for each eye.

The NP inside each goggle is monitored by a pressure sensor that is pneumatically connected to the respective goggle through a sense line. The NP and sense lines for each goggle are pneumatically connected proximal to the goggle cavity; this ensures that creation and monitoring of the NP level in each goggle can occur independently. The signal from each sensor is used in a separate Proportional-Integral-Derivative (PID) control loop for each pump so that the applied NP matches the value entered by the treating physician. If leaks exist at the interface between the seal and the patient's skin, NP is reduced and the PID controller increases rotational speed of the pump to counterbalance the leak and reestablish the prescribed NP level.

An additional differential pressure sensor is connected to each of the two independent sense lines to ensure that the differential signal matches the arithmetic difference between the NP levels set for the treatment of each eye and the actual NP levels sensed in each eye. An alarm is generated if the measured difference substantially departs from the arithmetic one.

For each independent NP line, a relief valve is also provided to mechanically limit the maximum allowable applied NP to a level < 40 mmHg. The device is meant to be used at home, worn overnight while the patient sleeps.

The Physicians App is an integral component to the FSYX™ Ocular Pressure Adjusting Pump System that allows the physician to program the FSYX™ Ocular Pressure Adjusting Pump with specific patient treatment parameters and to review patient wear information. Instructions on how to use the Physicians App preloaded onto a preconfigured laptop is available. Once programmed the FSYX™ Ocular Pressure Adjusting Pump can be activated by the patient at home via the touch-screen interface. Treatment programming is only possible via the Physicians App. The FSYX™ Ocular Pressure Adjusting Pump touch-screen interface only allows for

patients to 1) start the treatment; 2) view treatment settings; and/or 3) pause and resume the treatment or completely stop the treatment after pausing.

SUMMARY OF NONCLINICAL/BENCH STUDIES

Non-clinical testing for the FSYX™ Ocular Pressure Adjusting Pump System device included a biological safety evaluation, sterilization, packaging, and shelf-life testing, software and cybersecurity testing, electromagnetic compatibility (EMC) testing, performance testing, and human factors validation testing.

BIOCOMPATIBILITY

Biocompatibility testing was performed on the FSYX™ Ocular Pressure Adjusting Pump System by separating the components into three test groups: polymeric components, elastomeric components, and all components. The sample sets are as follows:

- Sample Set A consisted of the right seal (large), left seal (large), headstrap buckle, and para-tube tubing (polymeric components).
- Sample Set B consisted of the headstrap (elastomeric component).
- Sample Set C consisted of right seal (large), left seal (large), headstrap buckle, para-tube tubing, and headstrap (all components).

The biocompatibility assessment was performed in accordance with International Standard Organization (ISO) 10993-1: Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process, Part 5: Tests for in vitro cytotoxicity, - Part 10: Tests for skin sensitization. All tests were performed in accordance with Good Laboratory Practices (GLP). The information provided is in alignment with FDA's Biocompatibility Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". This evaluation was found to be acceptable.

STERILIZATION, PACKAGING, AND SHELF-LIFE

The device is provided as single-patient, multi-use and non-sterile. The use-life/shelf-life of the components have been tested and are defined as follows:

- Pump – 5 years (use-life)
- Battery – 500 cycles (use-life)
- Goggles – 1 month (use-life; 1 year shelf-life)

The labeling provides recommended instructions for cleaning of the goggles and Ocular Pressure Adjusting Pump unit. The sponsor provided testing to support the transport stability, the labeled shelf-life, and labeled cleaning instructions. The packaging requirements are compliant with standards ASTM D4169 and ISTA 2A. This evaluation was found to be acceptable.

SOFTWARE/CYBERSECURITY

The FSYX Ocular Pressure Adjusting Pump System is a cyber device per 524B(s) of the Food, Drug & Cosmetic Act. Balance Ophthalmics has followed the recommendations in the Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (fda.gov) (https://www.fda.gov/media/119933/download) guidance document (September 27, 2023).

The FSYX™ Ocular Pressure Adjusting Pump System is comprised of the FSYX Goggle, FSYX Ocular Pressure Adjusting Pump, and the Clinical Laptop with pre-installed FSYX Physician App (PhyApp) software. The device allows for the physician, using the FSYX PhyApp, to program a negative pressure treatment into the FSYX Ocular Pressure Adjusting Pump. A patient would then be able to wear the FSYX Goggle connected to the FSYX Ocular Pressure Adjusting Pump and activate the prescribed negative pressure treatment at night as a form of glaucoma treatment.

Software/Firmware Version:

- FSYX™ Ocular Pressure Adjusting Pump: v0.03:846
- FSYX™ Ocular Pressure Adjusting Pump System Physician App: v0.03:901

Balance Ophthalmics has classified their documentation level as "Enhanced Documentation" for both the FSYX™ Ocular Pressure Adjusting Pump firmware and the FSYX™ Ocular Pressure Adjusting Pump Physician App software. All major components of the device are controlled by software/firmware, which is responsible for the functionality, treatment program and user interface of the device. Balance Ophthalmics provided Ocular Pressure Adjusting Pump firmware and Physician App software documentation, outlining the software description, architecture, design specifications, risk assessments, and verification and validation testing to ensure proper system functions and essential performance are met. The software was developed and tested according to the recommendations in the Content of Premarket Submission for Device Software Functions (fda.gov) (https://www.fda.gov/media/153781/download) guidance document (June 14, 2023).

Software documentation and testing demonstrates that the FSYX Ocular Pressure Adjusting Pump System will operate in a manner described in the software requirements and design specifications. The hazard analysis characterized software and cybersecurity risks, including device malfunction, power/connectivity and other software failures, restricted treatment programming limits, warning pop-ups when negative pressure or treatment duration exceeds recommended levels, and unauthorized access and potential tampering by malicious end users. The submission describes verification and validation testing to address the potential hazards with satisfactory results. The cybersecurity documentation included a cybersecurity threat modeling and security system architecture, hazard analysis and mitigation controls information, vulnerability and penetration testing, a post-market vulnerability monitoring and upgrade/patches plan, other information for safeguarding the device during manufacturing and upon commercial distribution, and

warning and precaution information in the product labeling that ensures that the FSXY Ocular Pressure Adjusting Pump System is properly cyber secured. The software and cybersecurity evaluation were found to be acceptable.

EMC/WIRELESS, ELECTRICAL, MECHANICAL, AND THERMAL SAFETY AND RISK ANALYSIS

Electrical Safety and Electromagnetic Compatibility (EMC) testing has been performed as per the following recognized consensus standards and the results support electrical safety and electromagnetic compatibility.

- IEC 60601-1:2012: Medical electrical equipment – Part 1: General requirements for basic
  safety and essential performance

- IEC 60601-1-11: 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 62133: Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications.

- IEC 60601-1- 2 (2014): Medical Electrical Equipment – Part 1: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests

Testing was provided to address the electrical safety, pump life, electromagnetic compatibility, battery capacity/transport/safety, and Radio Frequency Identification (RFID) immunity, in support of the FSYX Ocular Pressure Adjusting Pump System. This evaluation was found to be acceptable.

PERFORMANCE TESTING: TESTING ON FSYX OCULAR PRESSURE ADJUSTING PUMP

The following tests were provided and found to be acceptable in support of the performance of the FSYX Ocular Pressure Adjusting Pump:

- Verification and Validation testing verified that the Ocular Pressure Adjusting Pump met the performance criteria defined in the Product Requirements Specification document.
- Pressure Release Valve Cycle Test testing was performed on 3 pressure release valves to verify the regulated release pressure of the valve and demonstrate over 100,000 pressure release cycles (per IEC 60601 section 9.7.7(h)).

- Over Pressure Valve Flow Test was conducted to verify that the design of the relief valve and the manifold it mounts into is such that, when the valve is activated, the system will provide the flow capacity to keep the system at or above -40mmHg.

PERFORMANCE TESTING: TESTING ON FSYX OCULAR PRESSURE ADJUSTING PUMP GOGGLES

The following tests were provided and found to be acceptable in support the performance of the FSYX Ocular Pressure Adjusting Pump System Goggles:

- Goggle Verification: Mechanical Integrity Testing was performed to document that the design of the goggles meet all requirements including:
    - Seal Integrity Test – This test was to verify that the MPD Goggle left and right assemblies, comprised of the seal, lens, pivots, and vacuum/sensor tubing, and male side of the connector can consistently hold an applied vacuum of -5 mmHg and -30 mmHg for a dwell time of 5 minutes without exceeding the set vacuum level ± 3 mmHg. In addition, following the 5-minute dwell at -30 mmHg, the "leak down" test was performed to verify that the pressure was above -5 mmHg after 30 seconds.
    - Tubing Joint Strength –Testing to verify that the tubing joints are able to withstand a minimum of 8 (6 lbs. time 1.5 safety factor) lbs. pull force while connected to the pump housing, after which they are not to leak past normal system specs.
    - Nose Bridge Joint Strength – This test is to verify that the nose bridge will withstand a tensile force of 2 lbs.
    - Lens Bonding Integrity Test – This test is to ensure that the adhesive used to bond the lenses to the seal bond will sustain an applied tensile force of 4 lbs.

- Goggle Kink Resistance testing was conducted to evaluate the kink resistance of the goggle tubing to verify the safety of the design of the co-axial tubing while there is a kink in the tubing. Additionally, testing demonstrates that the inner vacuum line, by design, becomes occluded before the sensor line in a kink scenario. This would prevent the vacuum pump from running beyond the target set-point, since the pump assembly senses the pressure in the goggles and therefore has the ability to regulate the pressure as intended. The angle under which a kink will be formed in both the sensor line and the vacuum line were tested to observe when each line becomes restricted when kinked.

PERFORMANCE TESTING: TESTING ON FSYX OCULAR PRESSURE ADJUSTING PUMP SYSTEM

Design Verification testing was performed to document the verification and validation assessment for the Equinox Multi Pressure Dial (MPD Gen 2) system. The MPD Gen2 is

identical to the subject device, FSYX Ocular Pressure Adjusting Pump System created by Balance Ophthalmics.

- Independent control of pressure for each goggle within ±1 mmHg.
- Exposure to pressure of -40 mmHg shall not exceed 10 seconds.
- Logging patient usage and compliance data gathered over a period of six months of daily 8-hour usage.
- Noise level of ≤40 Db at 1 meter distance during treatment with no leakage through the goggle seals.

This evaluation was found to be acceptable.

HUMAN FACTORS - USABILITY

All human factors/usability testing was conducted using the MPD System (Gen 2); however, this testing was found to be applicable to the FSYX Ocular Pressure Adjusting Pump System given that the technology is identical and all physician/patient materials reflect the updated name of the device.

A formative usability study was conducted to evaluate the patients' subjective ratings of ease of use during a home trial of the device, identify unanticipated use errors and confusion, and assess patient satisfaction/dissatisfaction with the device and with the Quick Start Guide. Additionally, the study was intended to evaluate the perceived effectiveness of the training for Technicians who will teach patients how to use the device, as well as evaluate the helpfulness of the Instructions for Use that was used by Technicians. The patient group in the formative test consisted of 13 patients diagnosed with glaucoma or ocular hypertension at three investigational sites in the United States. During one-on-one phone interviews, patients were asked to rate their experience with the tasks that were involved in using the goggles and pump. They were asked to rate each usability item on a 10-point scale, with 1 being a low rating (not easy) and 10 being a high rating (easy). In addition to asking patients about the usability of features, they were also asked about their attitude towards the device as a therapy for glaucoma and their satisfaction with various aspects of the goggles. Lastly, subjects were asked to comment on the comfort of the goggles, strap, and tube. It was concluded that the most serious risk of harm to patients is the device tubing. This risk was deemed to be adequately mitigated through patient training and labeling.

Following the formative usability study, a summative label comprehension and usability study was conducted. This Label Comprehension and Usability Validation Test study consisted of a 1-hour training session provided by a medical professional, a 1-hour post-training delay, and then a 1-hour testing session. The testing session consisted of two components: a written examination using a questionnaire and a recorded demonstration of device use by the test subject. The summative validation test was conducted with 20 test participants (11 patients, 9 caregivers). A standard function and task analysis was used to identify user tasks and they were categorized into non-critical, critical, and supercritical tasks. Only one supercritical task was identified: maintaining a seal on the

goggles. Based on the results of this Label Comprehension and Usability Validation Test, it was concluded that all risks have been lowered to an acceptable level; therefore, the results of the study demonstrate that the device user-interface supports the use-safety and effectiveness of use for the intended use.

SUMMARY OF CLINICAL INFORMATION

Clinical performance data were collected from a pivotal study (the "Artemis" study): "Negative Pressure Applied by the FSYX™ Ocular Pressure Adjusting Pump as an Adjunct Therapy for Lowering Intraocular Pressure in Subjects with Normal Tension Glaucoma."

Summary of the "Artemis" Study:

Overview:

The "Artemis" study was a prospective, longitudinal study conducted at 11 sites in the United States. Adults aged 40 years or older with diagnosed normal-tension glaucoma (NTG), screening intraocular pressure (IOP) between 12 and 21 mm Hg, and best-corrected visual acuity of 20/200 or better were enrolled. Eligible participants must have an unmedicated intraocular pressure (IOP) ≤21 mm Hg as demonstrated by either a washout of IOP-lowering medications or by lack of any documented unmedicated IOP > 21 mm Hg in either eye. Key exclusion criteria included those with allergies to silicone or latex, history of prior penetrating glaucoma surgery (e.g., trabeculectomy or aqueous shunt implantation), narrow anterior chamber anatomy, eyelid edema, festoons or excessive skin laxity, conjunctival chemosis, orbital anatomy precluding a proper goggles seal around both eyes, anticipated need for any ocular surgery, and/or ocular condition that would interfere with the interpretation of study outcomes or preclude safe participation in the study. During a 14-day "run-in" period prior to randomization, participants were instructed to begin at-home device use with gradual increase in device wear time. After completion of the "run-in" period, one eye per eligible participant was randomized to receive negative pressure (NP) application with the device while the fellow eye served as a control (zero NP). After randomization, participants were recommended to use the device for approximately six hours per night, five nights per week. An overnight, sleep lab visit was conducted within three weeks of randomization to assess supine IOPs prior to device use and during device use. Additional in-clinic follow-up visits were scheduled at Weeks 6, 12, 26, and 38. Final overnight sleep-lab and in-clinic visits were conducted around Week 52. Various scheduled IOP assessments for key effectiveness endpoints were planned to be performed with Goldmann applanation tonometry (GAT) at the slit-lamp biomicroscope and with pneumotonometry through modified "excursion goggles." Participants were allowed to remain on IOP-lowering medications during the study. NP programming was based on achieving a "reference" floor IOP of 6 mm Hg; however, investigators were given discretion over adjusting the study-eye NP level as needed based on data from device home use, participant comfort, and adverse events (AEs).

Because applanation-based IOP measurement cannot be performed while a patient is wearing the FSYX Ocular Pressure Adjusting Pump System goggles, study participants wore "Excursion goggles," a modified version of the FSYX Ocular Pressure Adjusting Pump System goggles intended for home use, during the application of NP at the in-clinic visits at the investigational

sites. The Excursion goggles were designed with an "access port" to allow for IOP measurements with a Reichert Model 30 pneumotonometer during NP application (refer to Figure 2 below).

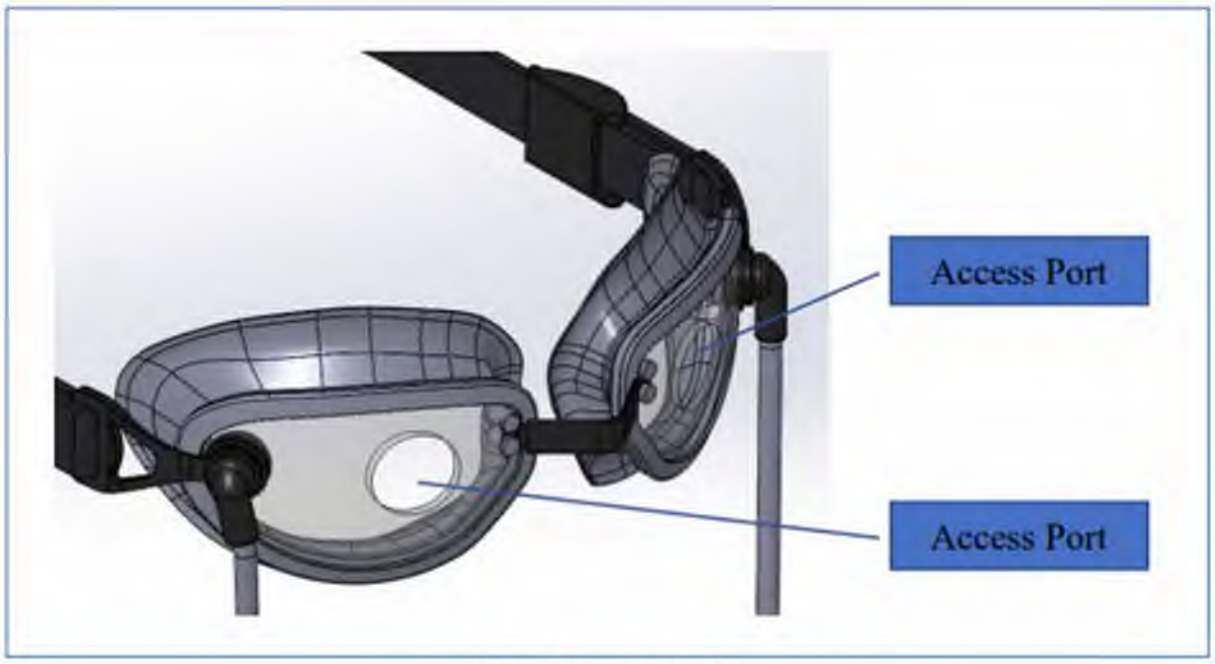

Figure 2: Excursion Goggles

The primary effectiveness endpoint was the proportion of eyes with IOP reduction of 20% or greater at 52 weeks (Visit 8) as measured via pneumotonometry with Excursion goggles worn from "before" to "during" application of negative pressure during in-clinic visit. The pre-specified hypothesis for the primary effectiveness endpoint is the proportion of eyes with IOP reduction of 20% or greater at 52 week (Visit 8) in-clinic visit is higher in the treatment group compared to the control group at a one-sided alpha level of 0.025. The corresponding statistical hypotheses are as follows:

Null Hypothesis: $\pi T1 - \pi F1 \leq 0$
Alternate Hypothesis: $\pi T1 - \pi F1 > 0$

The $\pi T1$ and $\pi F1$ are the proportion of eyes at the Week 52 in-clinic visit with IOP reduction $\geq$ 20% compared to baseline for the treated and control eyes, respectively. The secondary endpoint was the proportion of eyes in the mITT population with Week-52 sleep lab IOP (measured supine during NP application, via excursion tonometry, at 11:00 pm, 2:00 am, and 5:00 am, all within ± 60 minutes of the specified time point) reduction of 20% or greater compared to baseline IOP (measured prior to NP application). The pre-specified hypothesis for the secondary effectiveness endpoint is the proportion of eyes with IOP reduction of 20% or greater at 52 week (Visit 8) in sleep lab is higher in the treatment group compared to the control group at a one-sided alpha level of 0.025. The corresponding statistical hypotheses are as follows:

Null Hypothesis: $\pi T2 - \pi F2 \leq 0$
Alternate Hypothesis: $\pi T2 - \pi F2 > 0$

The $\pi T2$ and $\pi F2$ are the proportion of eyes at the Week 52 in sleep lab visit with IOP reduction $\geq 20\%$ compared to baseline for the treated (study) and control eyes, respectively.

Safety outcomes of interest included ocular, periocular, and non-ocular AEs, changes in best corrected distance visual acuity (BCDVA), slit-lamp biomicroscopy and ophthalmoscopy findings, changes in GAT IOP after completion of NP application, changes in visual field (VF), and changes in optical coherence tomography (OCT) imaging.

"Artemis" Study Results:

165 participants were enrolled. 55 were found ineligible or otherwise withdrew consent by the baseline or medication washout visit. 110 participants entered the "run-in" period and returned for the mid-run-in period visit (Day -7). During the "run-in" period, eight participants discontinued; four withdrew consent at Day -7 and four discontinued due to concerns with sleep-lab availability. 106 returned for the randomization visit (Day 0). Another eight participants were discontinued due to ineligibility or withdrawal of consent. 94 participants were randomized at Day 0. One randomized participant exited the study before receiving any study treatment; therefore, the modified intent-to-treat (mITT) population is comprised of 93 participants. 31 randomized participants (33%) failed to complete both the final sleep lab and the Week 52 in-office visit and two were reported with major protocol deviations; thus, a total of 62 participants (64.5%) completed the trial.

For the mITT population (N=93), the mean age was 62.4±10.7 years. 67.7% were women. The majority (68.8%; 64/93) were white, 13 (14.0%) were Black/African American, and 15 (16.1%) were Asian. Most participants (80.6%; 75/93) reported Ethnicity of not Hispanic/not Latino. The mean study-eye baseline IOP by GAT was 14.7±2.0 mm Hg (range 12 – 20 mm Hg) and the mean study-eye baseline visual field (VF) mean deviation (MD) was -4.03±4.86 dB (range -22.59 to +2.38 dB). Most participants were on either no (44.1%; 41/93) or only one (37.6%; 35/93) IOP-lowering medication at the time of screening. A small proportion of study and control eyes (5%; 5/93) had prior "minimally invasive glaucoma surgery" (MIGS). 15% of study eyes and 19% of control eyes had a prior glaucoma laser procedure. The median study-eye vertical cup-to-disc (C/D) ratio was 0.7 (range 0.3 to 0.95). The mean study-eye central corneal thickness (CCT) was 536.2±38.2 µm (range 413-640 µm).

Table1: Demographics (mITT and PP Populations)

	mITT (N = 93)	PP (N = 60)
Age at Consent	**(Years)**	**(Years)**
N	93	60
Mean ± SD	62.4 ± 10.7	61.4 ± 10.6
1st Quartile	54	53.8
Median	61	61
3rd Quartile	70	69.3
Min, Max	40, 85	40, 81
	n (%)	**n (%)**
Gender		
Male	30 (32.3%)	21 (35.0%)
Female	63 (67.7%)	39 (65.0%)
Race		
White	64 (68.8%)	44 (73.3%)
Black/African American	13 (14.0%)	9 (15.0%)
American Indian/Alaskan Native	0 (0.0%)	0 (0.0%)
Asian	15 (16.1%)	7 (11.7%)
Native Hawaiian/Pacific Islander	0 (0.0%)	0 (0.0%)
Other - Mestizo	1 (1.1%)	0 (0.0%)
Ethnicity		
Hispanic or Latino	18 (19.4%)	13 (21.7%)
Not Hispanic and not Latino	75 (80.6%)	47 (78.3%)
Study Eye		
OD	46 (49.5%)	32 (53.3%)
OS	47 (50.5%)	28 (46.7%)

The mean programmed NP level over the scheduled study visits ranged between -10.0 mmHg to -12.1 mmHg. Mean daily device wear time across study intervals ranged from 5.44 to 5.63 hours. Participants used the device on approximately 78% or more of the days between each in-clinic visit. At the initial sleep-lab visit, mean pre-NP IOP was 3.2 ± 2.8 mm Hg higher than the Day 0 in-clinic visit for the study eye and 1.7 ± 2.9 mmHg higher in the control eye. 41.25% (66/160) of eyes had >20% increase in supine, pre-NP IOP compared to the preceding in-clinic pre-NP IOP. At the Week-52 sleep-lab visit, mean pre-NP IOP was 2.4 ± 3.7 mmHg higher than the Week 52 in-clinic visit for the study eye and 1.9 ± 2.9 mmHg higher in the control eye. 34.4% (42/122) of eyes had >20% increase in supine, pre-NP IOP compared to the preceding in-clinic pre-NP IOP.

Table 3: Negative Pressure Settings for Subsequent Home Use (mITT Population)

	Day 0		Week 6		Week 12		Week 26		Week 38	
	Study	Control	Study	Control	Study	Control	Study	Control	Study	Control
Programmed NP, N	93	93	81	81	74	74	68	68	65	65
Mean	10.0	0.0	12.0	0.0	12.1	0.0	11.7	0.0	11.9	0.0
SD	2.4	0.0	3.1	0.0	3.0	0.0	3.1	0.0	3.8	0.0
1st Quartile	8.0	0.0	10.0	0.0	10.0	0.0	10.0	0.0	10.0	0.0
Median	10.0	0.0	12.0	0.0	12.0	0.0	12.0	0.0	11.0	0.0
3rd Quartile	11.0	0.0	14.0	0.0	14.0	0.0	14.0	0.0	14.0	0.0
Minimum	5.0	0.0	6.0	0.0	6.0	0.0	5.0	0.0	5.0	0.0
Maximum	16.0	0.0	20.0	0.0	20.0	0.0	20.0	0.0	20.0	0.0
Not Reported	0	0	0	0	0	0	0	0	0	0
Total	93	93	81	81	74	74	68	68	65	65
Programmed NP Change from Day 0, N	--	--	81	81	74	74	68	68	65	65
Mean	--	--	2.0	0.0	2.0	0.0	1.6	0.0	1.8	0.0
SD	--	--	2.9	0.0	2.8	0.0	3.2	0.0	4.0	0.0
1st Quartile	--	--	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Median	--	--	2.0	0.0	2.0	0.0	1.5	0.0	1.0	0.0
3rd Quartile	--	--	4.0	0.0	4.0	0.0	4.0	0.0	4.0	0.0
Minimum	--	--	-6.0	0.0	-6.0	0.0	-8.0	0.0	-8.0	0.0
Maximum	--	--	9.0	0.0	9.0	0.0	9.0	0.0	12.0	0.0
Not Reported	--	--	0	0	0	0	0	0	0	0
Total	--	--	81	81	74	74	68	68	65	65

Table 4: Ocular Pressure Adjusting Pump Home Use (mITT Population)

Visit Interval	Day 0 to Week 6	Week 6 to Week 12	Week 12 to Week 26	Week 26 to Week 38	Week 38 to Week 52
Nominal visit interval (days)	**42**	**42**	**98**	**84**	**98**
Days of OPAP use during the visit interval[^]					
Average days between visits	37.73	43.76	87.10	84.95	101.61
N	81	74	68	65	62
Mean	32.95	37.49	71.59	66.43	79.79
SD	8.87	11.43	19.82	23.10	23.17
Median	31.00	38.50	72.00	68.00	79.00
Minimum	14.00	8.00	5.00	2.00	20.00
Maximum	56.00	63.00	112.00	132.00	126.00
Average daily wear (in hours) of OPAP use during the visit interval[#]					
N	81	74	68	65	62
Mean	5.52	5.44	5.52	5.52	5.63
SD	1.22	1.42	1.55	1.43	1.33
Median	5.83	5.77	5.91	5.93	5.85
Minimum	2.71	2.01	1.01	2.05	2.02
Maximum[1]	7.65	7.82	8.92	8.98	8.34

[^]Days where treatment was dispensed for more than 20min.
[#]Sum of the usage of ONLY the days above 20min (any usage less than 20min is considered ZERO, and its corresponding day is not considered a usage day), divided by "Days of MPD use during the visit interval", divided by 3600 seconds, then converted into hours
[1] This statistic includes subjects who restarted treatment after an 8-hour treatment cycle was completed.

Table 5: Negative Pressure Settings and Wear Time at Each Study Interval (mITT Population)

	Negative Pressure Settings (mmHg)				
Avg Nightly Wear Time	0-6 Week Interval	6-12 Week Interval	12-26 Week Interval	26-38 Week Interval	38-52 Week Interval
0-3 Hours	14.0 ± 2.6 (4) [11.0, 17.0]	13.7 ± 2.8 (6) [10.0, 17.0]	12.7 ± 2.7 (6) [10.0, 17.0]	13.3 ± 4.4 (4) [9.0, 18.0]	12.3 ± 6.7 (3) [5.0, 18.0]
>3-4 Hour	12.9 ± 3.6 (7) [7.0, 19.0]	13.6 ± 3.1 (7) [10.0, 19.0]	11.7 ± 2.3 (7) [7.0, 14.0]	12.6 ± 4.7 (7) [6.0, 19.0]	11.3 ± 4.2 (3) [8.0, 16.0]
>4-5 Hour	13.4 ± 2.8 (15) [7.0, 17.0]	10.3 ± 3.3 (12) [6.0, 14.0]	11.8 ± 4.4 (8) [6.0, 19.0]	11.9 ± 3.4 (10) [6.0, 19.0]	11.1 ± 2.2 (10) [7.0, 14.0]
>5-6 Hour	12.5 ± 3.8 (21) [6.0, 20.0]	12.3 ± 3.4 (18) [6.0, 20.0]	12.1 ± 2.7 (16) [7.0, 18.0]	11.6 ± 3.9 (12) [7.0, 20.0]	11.6 ± 4.2 (20) [5.0, 20.0]
>6-7 Hour	12.7 ± 2.7 (29) [7.0, 18.0]	12.4 ± 2.5 (22) [7.0, 17.0]	11.9 ± 3.4 (22) [6.0, 20.0]	13.2 ± 3.6 (25) [5.0, 20.0]	12.9 ± 3.6 (18) [7.0, 20.0]
>7-8 Hour	12.2 ± 1.3 (5) [11.0, 14.0]	12.1 ± 2.4 (8) [7.0, 14.0]	12.9 ± 2.6 (8) [8.0, 16.0]	13.0 ± 4.8 (6) [7.0, 20.0]	13.2 ± 4.9 (6) [7.0, 20.0]
>8 Hours	--	--	11.0 ± NA (1) [11.0, 11.0]	11.0 ± NA (1) [11.0, 11.0]	10.0 ± 1.4 (2) [9.0, 11.0]

Data reported as Mean ±SD (N); [Min, Max].
Interval timing is aligned with dates used for the device wear time.
The NP level summarized is based on maximum reported NP within the visit interval.

The primary analyses for the primary and secondary effectiveness endpoints are based on the mITT population (all randomized participants who have at least one full application of NP; N=93). 33 of 93 are with missing primary effectiveness endpoint measurements, resulting in a 35.5% missing rate for the two study groups. With all missing values imputed as "non-responders," 58.1% (54/93) of study eyes achieved ≥ 20% reduction in IOP during NP application, as compared to 1.1% (1/93) of control eyes; this difference is statistically significant ($p < 0.001$). The secondary endpoint was tested after the primary effectiveness endpoint achieves statistical significance. For the secondary effectiveness endpoint, with all missing values imputed as "non-responders," 63.4% (59/93) of study eyes achieved ≥ 20% reduction in IOP compared to 3.2% (3/93) of control eyes; this difference is statistically significant ($p<0.001$).

Table 6: Proportion of Eyes with Week 52 IOP Reduction ≥ 20% During Negative Pressure Application (mITT Population)

IOP Reduction ≥ 20%	Study Eye	Control Eye	Difference (95% CI)[1]	P-value[2]
In-Clinic	58.1% (54/93)	1.1% (1/93)	57.0% (45.4%, 66.2%)	<.0001
Sleep Lab	63.4% (59/93)	3.2% (3/93)	60.2% (48.6%, 69.3%)	<.0001

Eyes with missing values were assumed to be non-responders.
[1] Bonett, D. G. and Price, R. M. (2012), Adjusted Wald Confidence Interval for a Difference of Binomial Proportions Based on Paired Data, J Educational and Behavioral Statistics, August 2012, Vol. 37, No. 4, pp. 479–488.
[2] McNemar Test with a two-sided significance level of 0.05

Table 7: Comparison of Percent Change in Mean Baseline Sleep Lab IOP and Corresponding In-Clinic Baseline IOP (mITT Population)

Visit	% IOP Difference from Corresponding In-Clinic Visit	Study Eye	Control Eye	All Eyes
Initial (Day 0) Sleep Lab	% IOP Difference**	22.7 ± 19.9 (80) 20.3 (-14.0, 74.4)	13.4 ± 20.1 (80) 9.6 (-23.3, 80.6)	18.0 ± 20.5 (160) 14.0 (-23.3, 80.6)
	Decrease	6/80 (7.5%)	19/80 (23.8%)	25/160 (15.6%)
	0-5% increase	11/80 (13.8%)	8/80 (10.0%)	19/160 (11.9%)
	>5-10% increase	9/80 (11.3%)	15/80 (18.8%)	24/160 (15.0%)
	>10-15% increase	7/80 (8.8%)	8/80 (10.0%)	15/160 (9.4%)
	>15-20% increase	6/80 (7.5%)	5/80 (6.3%)	11/160 (6.9%)
	>20-25% increase	9/80 (11.3%)	8/80 (10.0%)	17/160 (10.6%)
	>25-30% increase	6/80 (7.5%)	5/80 (6.3%)	11/160 (6.9%)
	>30% increase	26/80 (32.5%)	12/80 (15.0%)	38/160 (23.8%)
Final (Week 52) Sleep Lab	% IOP Difference**	16.4 ± 23.4 (61) 13.5 (-26.9, 73.9)	13.0 ± 17.8 (61) 11.9 (-25.0, 68.6)	14.7 ± 20.8 (122) 12.8 (-26.9, 73.9)
	Decrease	16/61 (26.2%)	16/61 (26.2%)	32/122 (26.2%)
	0-5% increase	3/61 (4.9%)	3/61 (4.9%)	6/122 (4.9%)
	>5-10% increase	6/61 (9.8%)	10/61 (16.4%)	16/122 (13.1%)
	>10-15% increase	8/61 (13.1%)	5/61 (8.2%)	13/122 (10.7%)
	>15-20% increase	5/61 (8.2%)	8/61 (13.1%)	13/122 (10.7%)
	>20-25% increase	5/61 (8.2%)	4/61 (6.6%)	9/122 (7.4%)
	>25-30% increase	1/61 (1.6%)	4/61 (6.6%)	5/122 (4.1%)
	>30% increase	17/61 (27.9%)	11/61 (18.0%)	28/122 (23.0%)

*% IOP difference from In-Clinic calculated as Pre-NP IOP value from sleep lab minus Pre-NP IOP value from in-clinic, divided by pre-NP; thus, a negative number is indicative of lower pre-NP IOP at the sleep lab.
** Data displayed as Mean ± SD (N); Median (Min, Max).

The relationship between the change in IOP between pre-NP and during-NP measurement and the programmed NP level was variable. At the final in-clinic visit, the mean "dose-response" (percent change in IOP between pre-NP and during-NP measurement divided by the programmed NP level) was 58.3% ± 23.8% (median 53.4%; range 7.1% to 116%; interquartile range 45.5% to 75%).

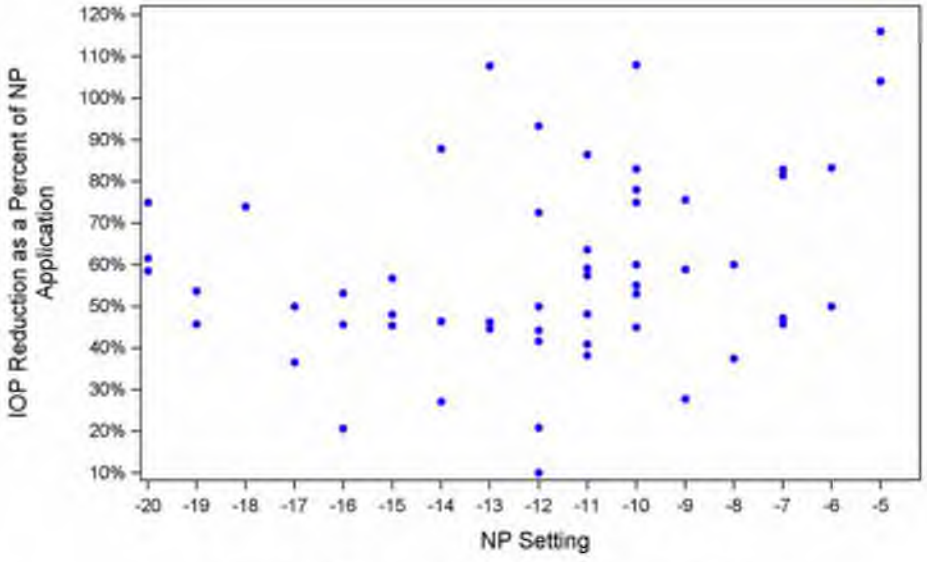

Figure 1: IOP Reduction as Percent of NP Application

The mean study-eye, in-clinic IOPs by GAT prior to NP application were 14.4 mm Hg, 14.7 mm Hg, and 14.4 mm Hg at Day 0, Week 26, and Week 52, respectively. The mean study-eye, in-clinic IOPs by GAT immediately after NP application were 13.9 mm Hg, 13.7 mm Hg, and 14.2 mm Hg at Day 0, Week 26, and Week 52, respectively. In study eyes, the mean percent changes from pre-NP to post-NP IOP by GAT were -3% (range -36% to +23%), -6% (range -40% to +23%), and -1% (range -39% to +25%) at Day 0, Week 26, and Week 52, respectively.

39 and 17 ocular AEs were reported in 25 study eyes and 13 control eyes, respectively. 24 ocular AEs in 19 study eyes were determined to be device-related. The most frequently occurring AEs in study eyes were lid edema (11 eyes; 11.8%), mild signs and symptoms of dry eye (5 eyes; 5.4%), mild to moderate conjunctival hyperemia (4 eyes; 4.3%), and mild to moderate eye pain (3 eyes; 3.2%). Transient eye pain related to NP application during device wear was reported in three study eyes.

20 and seven periorbital AEs were reported for 17 study eyes and seven control eyes, respectively. All study-eye periorbital AEs were device-related and were resolved by study completion or by cessation of device use. The most frequently reported periorbital AEs in study eyes were mild to moderate periorbital edema (12 eyes; 12.9%) and mild periorbital contact dermatitis (4 eyes; 4.3%). Of the 37 participants with ocular or periorbital AEs, 59.5% (22/37) had a programmed NP level higher than the protocol-recommended programming. No signs or symptoms of hypotony were reported.

Two participants experienced mild to moderate headaches during device use. One participant reported a rash in the upper left cheek area. In addition, periorbital edema, periorbital contact dermatitis, and mild device-associated headache were reported by seven participants during the "run-in" period. Eight participants used the device with NP setting of -17 to -20 mm Hg for at least 26 weeks of the study. Of these eight, three experienced AEs (mild periorbital edema and dry eye signs and symptoms). Two participants achieved average nightly wear >8 hours during at least one study period; of these two, one reported headache, lid erythema, and periorbital edema on Day 0 and several NP adjustments were made throughout the study.

Table 8: Ocular and Periorbital Adverse Events Reported After Study Randomization (Safety Population)

Ocular or Periorbital Adverse Event:	Study Eyes (N=93)			Control Eyes (N=93)		
	# of Reports	# of Eyes	% of Eyes	# of Reports	# of Eyes	% of Eyes
Any ocular AE	39	25	26.9%	17	13	14.0%
Anterior basement membrane dystrophy	1	1	1.1%	1	1	1.1%
Conjunctival chalasis	0	0	0	1	1	1.1%
Conjunctival hyperemia	4	4	4.3%	2	2	2.2%
Epithelial defect	1	1	1.1%	0	0	0
Eye pain	4	3	3.2%	0	0	0
Eye pain secondary to ocular trauma	0	0	0	1	1	1.1%
Floater	1	1	1.1%	0	0	0
Iritis	1	1	1.1%	1	1	1.1%
Lid edema	12	11	11.8%	1	1	1.1%
Lid erythema	2	2	2.2%	1	1	1.1%
Loss of BCDVA ≥ 10 letters from baseline	2	2	2.2%	2	2	2.2%
Meibomian gland dysfunction	1	1	1.1%	1	1	1.1%
Nuclear sclerotic cataract	1	1	1.1%	1	1	1.1%
Posterior vitreous detachment	2	2	2.2%	0	0	0
Symptoms and signs of dry eye	6	5	5.4%	5	5	5.4%
Visual disturbance	1	1	1.1%	0	0	0
Any periorbital AE	20	17	18.3%	7	7	7.5%
Cherry hemangioma	0	0	0	1	1	1.1%
Nasal abrasion	1	1	1.1%	0	0	0
Periorbital contact dermatitis	4	4	4.3%	3	3	3.2%
Periorbital edema	12	12	12.9%	1	1	1.1%
Periorbital folds above eyebrows	1	1	1.1%	1	1	1.1%
Periorbital pain	2	2	2.2%	1	1	1.1%

AE=adverse event; BCDVA=best-corrected distance visual acuity.
% = n/N × 100%.
Includes events that occur on the date of randomization or later. An eye could report multiple events. No (0) events were serious.

Table 9: Device-Related Ocular and Periorbital Adverse Events (Safety Population)

Related Adverse Event:	Study Eyes N=93			Control Eyes N=93		
	# of Reports	# of Eyes	% of Eyes	# of Reports	# of Eyes	% of Eyes
Any device-related ocular or periorbital AE	44	32	34.4%	11	10	10.8%
Any device-related ocular AE	24	19	20.4%	5	4	4.3%
Conjunctival hyperemia	3	3	3.2%	1	1	1.1%
Eye pain	3	3	3.2%	0	0	0.0%
Lid edema	12	11	11.8%	1	1	1.1%
Lid erythema	2	2	2.2%	1	1	1.1%
Symptoms and signs of dry eye	3	3	3.2%	2	2	2.2%
Visual disturbance	1	1	1.1%	0	0	0.0%
Any device-related periorbital AE	20	17	18.3%	6	6	6.5%
Nasal abrasion	1	1	1.1%	0	0	0.0%
Periorbital contact dermatitis	4	4	4.3%	3	3	3.2%
Periorbital edema	12	12	12.9%	1	1	1.1%
Periorbital folds above eyebrows	1	1	1.1%	1	1	1.1%
Periorbital pain	2	2	2.2%	1	1	1.1%

% = n/N × 100%.
AE = adverse event.
Includes events that occurred on the date of randomization or later. Multiple events could be reported for an eye.
Device-related consists of events considered possibly, probably, or definitely related.

Worsening of VF MD by ≥2.5 dB was reported in seven participants at Week 26 (four study eyes and five control eyes) and in four participants at Week 52 (three study eyes and three control eyes). The VF data from four of the seven (57.1%) Week-26 participants and from two of the four Week-52 participants (50.0%) were determined to be insufficient for analysis. In the remaining three of the seven Week-26 participants, no glaucoma progression was determined for either eye. In the remaining two Week-52 participants, glaucoma progression was not detected in the study eyes. Of the 62 participants who completed the Week-52 visit, the study-eye mean retinal nerve fiber layer (RNFL) thickness on OCT imaging (77.9 ± 13.6 μm) was unchanged between baseline and Week 52. RNFL thickness thinning of >5 μm was reported in 8% of study eyes and 11% of control eyes; none of these eyes had reported VF loss.

POSTMARKET EVALUATION

A postmarket study will be conducted to determine the long-term safety of the device over a three-year period. Assessments will include visual field (VF), optical coherence tomography (OCT), and all ocular and periocular safety events. Additionally, data from a fit-for-purpose patient-reported outcome measure (PROM) to evaluate the impact of the use of the device on certain aspects of health-related quality of life (HRQOL) will be collected. The study will evaluate the performance of the device in the real-world population as defined by the indications for use and per the instructions for use.

LABELING

The labeling is sufficient and satisfies the requirements of 21 CFR 801.109 for prescription devices.

Device instructions for use are provided for patient and prescribing users of the device separately. The FSYX Ocular Pressure Adjusting Pump System Patient Instructions for Use includes steps on how to connect the goggles to the FSYX Ocular Pressure Adjusting Pump, wear the goggles, start and end treatment, and adjust and clean the goggles. To supplement the patient instructions for use, a FSYX Ocular Pressure Adjusting Pump System Quick Start Guide and FSYX Ocular Pressure Adjusting Pump System Goggle Fitting Guide are also provided to the patient.

The FSYX Ocular Pressure Adjusting Pump System Healthcare Professionals Instructions for Use includes steps for establishing patient treatment settings (e.g., recommended duration and negative pressure programming), and patient training. A FSYX Ocular Pressure Adjusting Pump System Physicians Application Quick Start Guide is also provided to prescribers of the device.

Several product warnings are included in the labeling that carefully specify that treatment durations between 6 and 8 hours and/or treatments at NP levels of ≥ -17 mm Hg should be proceeded with caution.

The labeling also includes a summary of the clinical study procedures, patient population, and results.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with the use of an external ocular negative pressure system and the measures necessary to mitigate these risks.

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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

The risks of the device are based on data collected in the Artemis study as summarized above. They include ocular and non-ocular adverse events (AEs) such as eyelid edema, periorbital edema, conjunctival hyperemia, and eye pain. These AEs resolved with discontinuation of device use.

The probable benefits of the device are also based on data collected in the Artemis study. They include temporary lowering of intraocular pressure (IOP) while the device is in use and a non-pharmacologic and non-surgical option to lower IOP. IOP is a surrogate endpoint for the treatment of glaucoma (a chronic optic neuropathy that can lead to irreversible vision loss), because it is the only known modifiable risk factor for glaucoma. It has not been demonstrated whether these benefits will result in halting or slowing of the progression of glaucoma. This is a source of uncertainty. Other sources of uncertainty include missing data for the key effectiveness endpoints, the wide variability in nightly wear time among participants, and the lack of information on harmful impacts on quality of life and sleep and on long-term ocular effects from chronic application of negative pressure.

Additional factors considered in determining probable risks and benefits for the FYSX Ocular Pressure Adjusting Pump System device included uncertainty, risk mitigation, the novelty of the technology, and deliberations during the meeting of the Ophthalmic Devices Panel of the

Medical Devices Advisory Committee held on March 21, 2024. The panel recommended a postmarket study to address some of the sources of uncertainty noted above.

Patient Perspectives

This submission did not include specific information on patient perspectives for this device. The postmarket surveillance plan will include the collection of data to evaluate the impact of the use of the device on certain aspects of health-related quality of life (HRQOL).

Benefit/Risk Conclusion

In conclusion, given the available information, for the following Indications for Use statement:

> 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.

The probable benefits outweigh the probable risks for the FSYX Ocular Pressure Adjusting Pump System. The device provides benefits and the risks can be mitigated by the use of general controls and the identified special controls.

CONCLUSION

The De Novo request for the FSYX Ocular Pressure Adjusting Pump System is granted and the device is classified as follows:

> Product Code: QQJ
> Device Type: External ocular negative pressure system
> Regulation Number: 21 CFR 886.5000
> Class: II