



April 30, 2026

Balance Ophthalmics Inc.
Gary Mocnik
V.P. RA/QA and Regulatory Consultant
3101 W 57th Street
Sioux Falls, South Dakota 51708

Re: K252455

Trade/Device Name: FSYX™ Ocular Pressure Adjusting Pump
Regulation Number: 21 CFR 886.5000
Regulation Name: External Ocular Negative Pressure System
Regulatory Class: Class II
Product Code: QQJ
Dated: March 23, 2026
Received: March 24, 2026

Dear Gary Mocnik:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm> identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the 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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 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>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems>.

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

Sincerely,

BENNETT N. Digitally signed by
WALKER -S BENNETT N. WALKER -S
Date: 2026.04.30
11:43:59 -04'00'

for Claudine Krawczyk
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252455

?

Please provide the device trade name(s).

?

FSYX Ocular Pressure Adjusting Pump

Please provide your Indications for Use below.

?

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.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

**510(k) SUMMARY
K252455**

I. Submitter Information

510(k) Owner: Balance Ophthalmics Inc..
3101 W 57th Street
Sioux Falls, SD 51708

Contact Person: Gary Mocnik
GSM Services Inc..
49 Coastal Oak
Aliso Viejo CA 92656
gary@gsmervicesus.com
949.433.0413

Date Prepared: April 29, 2026

II. Device Name and Classification

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

III. Predicate Device and Reference Devices

Predicate Device

FSYX Ocular Pressure Adjusting Pump System (DEN230055)

IV. Device Description

The FSYX Ocular Pressure Adjusting Pump System is comprised of a programmable pump and a set of goggles. The two devices are mechanically and pneumatically connected via the tubing system that is integral to the goggles.

The FSYX Pump is a device which houses two miniature diaphragm pumps that produce independent negative pressure (NP) levels for each eye. The pumps in the device are connected to a manifold that pneumatically interfaces to the connector integral to the tubing system of the goggles. The manifold also mechanically and pneumatically connects three pressure sensors: two sensors are used for measuring the NP in each of the goggles; an additional differential pressure sensor is connected to each of the two independent sense lines to ensure that the differential pressure 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; this information is used to limit the applied NP within safe values, and treatment is interrupted if the measured difference substantially departs from the arithmetic one.

The FSYX Goggles, which are provided in 3 sizes (small, medium, and large) are designed to comfortably fit and seal around the eyes of patients with a wide variety of facial features, creating a chamber in which negative pressure (NP) can be created and maintained. The goggles include a tubing system that allows the creation and sensing of NP through separate lumens and independent treatment parameters for each eye. A head strap is included with the goggles to facilitate reliable positioning on the patient's face during sleep. The goggles can be connected to and disconnected from the FSYX Pump to allow for periodic cleaning and replacement.

DEVICE MODIFICATIONS

Following is a list of modifications compared to the system approved under from DEN230055.

Activation of a Cellular module that was previously installed and tested, but not utilized in the system approved in DEN230055, for unidirectional (i.e. from the device only) transmission of usage data to Balance's Cloud Platform.

The FSYX Pump is equipped with a cellular module for the transmission of usage data to Balance's Cloud Platform. The Cellular Module is a discrete module, functionally independent from the microprocessor controlling the safety and effectiveness of the treatment delivered by the FSYX Ocular Pressure Adjusting Pump.

As the FSYX Pump does not store any Protected Health Information (PHI), the cellular module will not transmit any PHI from the device to the Cloud Platform.

Data transmission will be unidirectional, i.e.:

- From the FSYX Pump microprocessor to the onboard Cellular Module only, and
- From the FSYX Pump Cellular Module to the Cloud Platform only.

As such, no PHI will be received, and subsequently stored, by the FSYX Pump. The unidirectional nature of the communication will also make the system inherently resilient against cyberattacks and potential attempts to remotely modify the treatment parameters. The independent nature of the microprocessor and Cellular Module will also ensure that any potentially successful Denial of Service (DOS) attack will only affect connectivity without impairing the effectiveness or safety of the treatment delivered by the FSYX Pump.

Finally, data communication will only be active when the device is not in use, and it is being recharged. When the device is being used, the Cellular Module will be kept unpowered. When the device is not in use and it is being recharged, the Cellular Module will be briefly turned on by the microprocessor to transmit usage data and it will be unpowered immediately after transmission, effectively reducing the attack surface of the system. In other words, the system is not continuously online: the Cellular Module is turned on only for a short time when data transmission is needed.

Of note, the data transmission process does not require any action from the patient, the device does not present any additional GUI element to the patient to initiate data transmission, and the process is completely invisible to them.

Use of the Care App on a user-provided Windows Personal Computer.

The Physician App cleared on DEN230055 is used for programming the FSX Pump and reviewing usage data; it is distributed as part of a cybersecure laptop setup provided by Balance. Additionally, the App does not record, access, receive, visualize, or distribute any PHI, and the FSX Pump must be physically connected to the Clinical Laptop via a USB cable in order for it to be programmed or visualize usage data. The App can be used by anyone allowed to fulfill a valid prescription, such as a Physician, an Eye Care Professional, a Nurse, or a Technician such as a durable medical equipment (DME) supplier employee.

The new version of the App (part of this submission) will be called the Care App and will run locally on any Windows 10/11 computer provided by the user fulfilling a prescription or reviewing usage data, rather than exclusively on a Balance provided laptop. Access to the App will be controlled by a user log in system (see below for more details) and usage data will be served by the Cloud Platform.

When used by an eye care professional, after successful log in, the App will display a list of patients treated by/associated to the user. The patients will be identified by a Balance ID and basic PHI (e.g. the patients' names). The eye care professional will only be able to review the usage data of the patients, served by the Cloud Platform, without the need for a FSX Pump to be physically connected to the computer. Importantly, a physician will not be able to directly change treatment parameters programmed in a FSX Ocular Pressure Adjusting Pump.

When used by a DME supplier employee, authorized to fulfill medical device prescriptions, after successful log in, the App will display a list of patients associated to the DME supplier. The patients will be identified by a Balance ID and basic PHI (e.g. the patients' names). The user will be able to review usage data and will also be able to fulfill prescriptions by assigning a FSX Ocular Pressure adjusting Pump to the appropriate patient and programming the prescribed treatment parameters (negative pressure and duration). Importantly, physical connection to the computer will always be needed in order to program or modify treatment parameters of a FSX Pump, and no PHI will be transferred to or stored by the FSX pump.

User Access to the Care App for Eye Care Professional, or DME supplier authorized employee controlled by Balance's Cloud platform

As stated before, access to the Care App will be controlled by providing users with a personal username and password. The credentials will be issued by, controlled by, and maintained within Balance's Cloud Platform. Access to the Care App will be granted only to users with valid log in credentials that will be verified against the ones stored in the Cloud Platform. The level of access to the Care App will be controlled by the role assigned to each particular user: eye care professionals will be able to remotely review device usage, while DME supplier employees will also be able to change treatment parameters when a device is physically connected to the PC.

The list of the patients treated by each eye care professional or managed by each DME supplier will also be controlled through the Cloud Platform.

Finally, the Care App will not be freely available to download. It will be available only to users, through logging in on Balance's Online Portal. Login credentials will be issued to users after they

submit a request to Balance, and each copy of the Care App will be “watermarked” and tied to the credentials of the user downloading it.

Inclusion of basic PHI in Balance’s Cloud Platform (i.e. Patient Names)

Each patient will be identified in Balance’s Cloud Platform exclusively through their names. Those names will be visible only to their treating physician, nurse, technician, or their managing DME supplier, and only through the Care App, after successful log in. Patient data will not be stored locally on the computer running the Care App and it will be eliminated from memory upon termination of the Care App session.

Removal of relief valves from the manifold sub-assembly

The design approved under DEN230055 provided, as part of the manifold sub-assembly, a relief valve for each independent NP line; such valves have the function of mechanically limiting the maximum allowable applied NP to a level < 40 mmHg, as defined by the device essential performance requirements (i.e. *The FSYX Ocular Pressure Adjusting Pump shall not generate pressure below -40 mmHg for longer than 10 seconds*).

The updated manifold design removes the valves as the essential performance requirements can be reliably met with other means:

- The pressure control system can effectively regulate pressure levels below -40mmHg and return the NP applied to the patient’s eyes above said threshold well within the time requirement of 10 seconds as specified by the essential performance requirements.
- The redundant pressure measurement system part of the design approved under DEN230055 is unchanged, allowing the same level of integrity and reliability of pressure measurements.
- In the event of a software malfunction, the system implements a hardware watchdog that disables the vacuum pumps and allows the NP to return to values above -40mmHg well within the required 10 seconds timeframe.

The removal of the relief valves is supported by a detailed Fault Tree Analysis as well as direct testing under different fault case scenarios.

Update to Labeling to reflect the inclusion of a cellular module to the FSYX Ocular Pressure Adjusting Pump and the introduction of the Care App

Compared to the device approved under DEN230055, device labeling is modified by adding the cellular module FCC ID number and FCC Rule part 15 compliance language.

The Patient and Eye Care Professional IFUs of the FSYX Ocular Pressure Adjusting Pump with cellular connectivity are modified to include additional information regarding the cellular connectivity capability; such additional information include:

- An updated cybersecurity notice at the beginning of the IFUs, and an updated cybersecurity section
- A section explaining how cellular connectivity works and what data is communicated
- A section covering the technical specifications of the cellular technology used

Additionally, the section of the Eye Care Professional IFU relative to the Care App is updated to reflect the refreshed look of the Graphical User Interface, and to explain the benefits of a cellular-system, which allows the Care App user to review usage data through Balance’s Cloud Platform, without the need for the device to be physically connected to a computer.

Finally, the Care App Quick Start Guide is updated to reflect the appearance and functionality of the Care App.

V. Intended Use and Indications for Use

Indications for Use

The FSYX™ Ocular Pressure Adjusting Pump System 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.

Intended Use

The intended use of the FSYX™ Ocular Pressure Adjusting Pump System is an 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. There is no significant difference between the primary predicate intended use and the device modifications described in this submission.

VI. Comparison of Technological Characteristics with the Predicate Device

The principle of operation for the FSYX Ocular Pressure Adjusting Pump System and the primary predicate are the same: 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. The only difference is the modification of the over pressure control feature and the addition of 5G communications for physician/medical professional review of usage information in the proposed device.

	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
Manufacturer	Balance Ophthalmics Inc. 3101 W 57th Street Sioux Falls, SD 51708	Balance Ophthalmics Inc. 3101 W 57th Street Sioux Falls, SD 51708
510(K) Clearance Date		
Regulation Number	886.5000	886.5000
Product Code(s)	QQJ applicator, negative pressure, external, ocular	QQJ applicator, negative pressure, external, ocular

	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
Indication for Use	Same as predicate	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.
Principle of Operation	Same as primary predicate	The FSYX System is designed to allow the application and monitoring of bilateral Negative Pressure (NP) in the microenvironment in front of a patient's eyes. The device can apply NP ranging from -5 mmHg to -20 mmHg, and treatment values can be programmed independently for each eye.
FSYX Pump		
<ul style="list-style-type: none"> Housing 	Same as predicate	Enclosure is made of two polycarbonate halves that mate and create a protective shell for the electrical and pneumatic components of the pump.
<ul style="list-style-type: none"> Touch screen 	Same as predicate	The touch screen allows for the display of a graphical user interface and the interaction between the patient or caregiver and the device.
<ul style="list-style-type: none"> Display board 	Same as predicate	The graphics controller is implemented on the LCD board and connects to the LCD module on one side and the main board, through a multi-pin connector, on the other side

	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
<ul style="list-style-type: none"> Main board 	Same as predicate with the addition of the SD memory card and the SIM card of the cellular module are connected to the main board.	The main board is the central part of the electromechanical design of the FSYX OPAP pump; the micro controller that implements all the main functions is located on the main board. Sensors, motors, the on/off button, the battery, the liquid crystal display (LCD) board, the universal serial bus (USB) connector, and the cellular module are all connected to the main board.
<ul style="list-style-type: none"> Battery 	Same as predicate	Rechargeable 3.7 volt battery to power the FSYX Pump for a minimum of 12 hours
<ul style="list-style-type: none"> Manifold 	Same as predicate	The manifold sub-assembly is the central part of the pneumatic design. Pumps, sensors, a pneumatic plug, and the goggles connector pneumatically and mechanically connect to it. The various pneumatic paths are all implemented in the manifold, which is made of a silicone elastomer to facilitate pneumatic sealing with the various connected components and to dampen vibrations coming from the motors
Maximum Single Fault Pressure:	Same as predicate Relief Valves part of the predicate design are removed. The design meets the same Essential Performance requirement as predicate design under single fault condition, as evidenced by the Fault Tree Analysis RM-013, TR-088, and TR-095.	40mmHg for < 10 secs (Essential Performance)



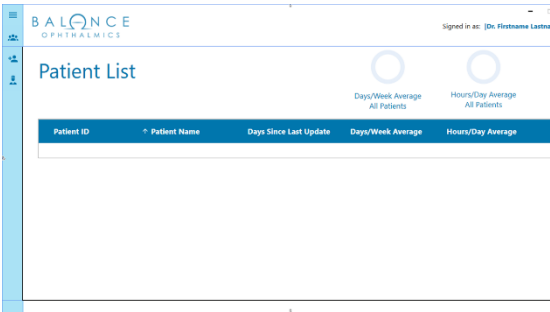
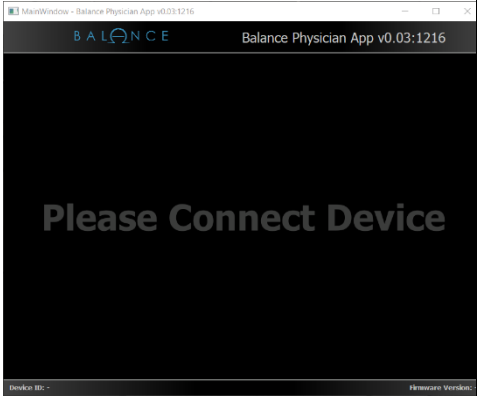
	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
Pump Unit (USB Power Wall Adapter) AC input range: DC output range: Typical power consumption: Maximum power consumption: Pump is powered by Lithium Polymer Battery	Same as predicate	100-240V, 50-60Hz, 0.3A 5V, 2A 3VA 6VA 3.7V 2400mAh
Environmental Conditions Operating temperature: Operating humidity: Operating altitude: Storage and transport temperature: Storage and transport humidity:	Same as predicate	+5°C to 35 °C 10-95%, non-condensing Sea level to 2,591 m (8500 ft.) -20°C to +60°C 10% - 95% non -condensing

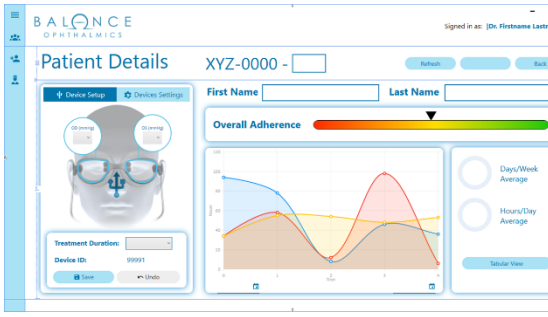
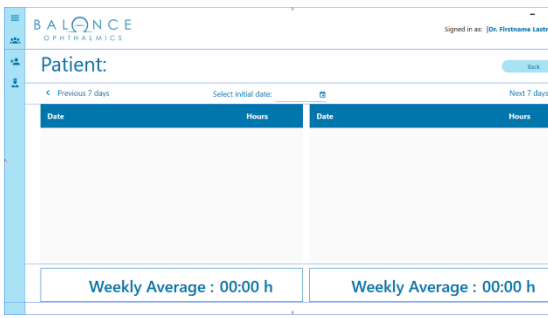
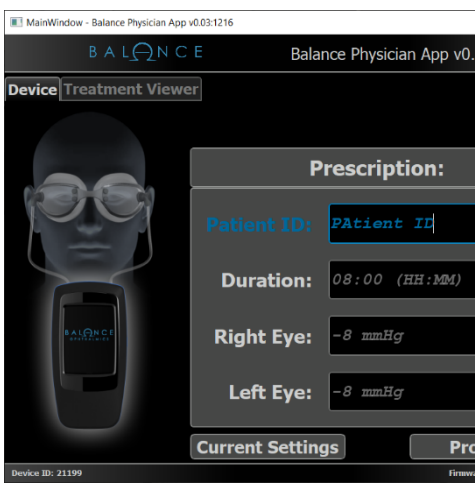
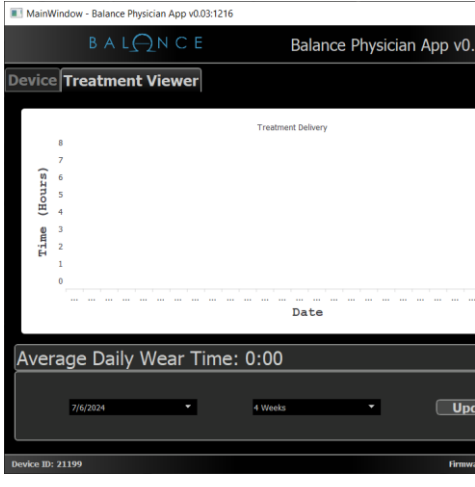
	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
Electromagnetic Compatibility EMC requirements	Same as predicate	According to IEC60601-1-2 4th Edition
Classification: IEC 60601-1:	Same as predicate	Class II (double insulation), Type BF
Operating pressure range:	Same as predicate	-5 to -20mmHg
Maximum Single Fault Pressure:	Same as predicate	-40mmHg for < 10 secs
Physical – Pump Dimensions (H x W x D): Weight: Housing Material: Pump Button Material:	Same as predicate	4.5in x 2.7in x 1.4in 0.3 lbs. Makrolon Polycarbonate Makrolon Polycarbonate
FSYX Goggles	Same as predicate There are no changes to the goggles from those described in DEN230055	The FSYX OPAP goggles come in 3 different sizes (Small, Medium, and Large) to accommodate patients with a large range of facial anthropometric features.


	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
<ul style="list-style-type: none"> • Lens and seal 	Same as predicate	<p>Goggle lenses are cut from polycarbonate lens blanks and have an anti-fogging coating on the inside surface to prevent fogging during use.</p> <p>The goggle seals create an air-tight interface between the face and the lenses. They are made of a Shore A 50 biocompatible Liquid Injection Molded silicone rubber. The design of the silicone seals is based on 3 factors - mechanical support, lens interface, and anthropometric interface</p>
<ul style="list-style-type: none"> • Nose bridge 	Same as predicate	The left and right lenses are connected by a nasal bridge assembly which, in its functional form, is a deformable stainless-steel component connected to the lenses
<ul style="list-style-type: none"> • Pivots 	Same as predicate	On the lateral periphery of the lenses, the tubing system is connected through two pivot assemblies. The pivots can rotate and maintain airtightness at the same time. The rotation of the pivots is a design feature that allows multiple ways of routing the tubing system around the patient's head
<ul style="list-style-type: none"> • Headgear 	Same as predicate	The headstrap consists of a stretchable strap with a longitudinal split, which allows for routing around the occipital and the parietal bones for a secure fit; 2 buckles are located temporally for fitting and adjustment headstrap length.

	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
Head Strap Dimensions (Length x W x D): Weight: Material: Cleanable:	Same as predicate	22.75in x 0.67in x 0.08 0.01 lbs. Nylon/Spandex Hand-washable
• Tubing	Same as predicate	The tubing system consists of two external tubes bonded together and two smaller tubes slipped inside the larger tubes. The cavity between the inner surface of each outer tube and the outer surface of each corresponding inner tube creates a pneumatic path referred to as the sense line; each goggle is connected to an individual and independent sense line. Each inner tube creates a pneumatic path referred to as the NP line; each goggle is connected to an individual and independent NP line.
Tubing Dimensions (Length x OD x ID): Weight: Material: Cleanable	Same as predicate	3Ft x 0.125in x 0.0625in 0.05 lbs. Polyurethane No
• Connector	Same as predicate	The connector consists of multiple components that have 2 main functions: pneumatic connection of the 2 sense lines and two NP lines to the corresponding features of the manifold, and mechanical connection of the connector to the FSYX System pump.

	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
Physical – Goggles, Head Strap, Lenses, Seals, Tubing Goggles Dimensions (H x W x D): Weight: Cleanable:	Same as predicate	2.25in x 6.75in x 1.5in 0.17 lbs. Yes, Isopropyl Alcohol
Patient Contact Materials	Same as predicate	Utilizes biocompatible materials
Programming and Data Display Application Software	The Care App , like the Physician App approved under DEN230055, is a Windows -compatible software application used by clinical staff to program the NP parameters (therapy duration and NP level for each eye) for the connected FSYX Pumps. Compared to the Physician App approved under DEN230055, the Care App part of this 510(k) application provides a refreshed user interface and the ability to connect to Balance’s Cloud Platform system for the secure upload, download, and visualization of usage data. Additionally, a user log in is required to access the Care App, as this piece of software is intended to securely run on Windows PCs not controlled or provided by Balance, and it is designed to control access to usage data stored in Balance’s Cloud Platform.	The Physician App is Windows compatible software provided on a dedicated laptop used by clinical staff to program the NP parameters (therapy duration and NP level for each eye) for the FSYX OPAP pump. The Physician App can also be used to download usage information from the connected pumps, which can be saved in a local database. Pump usage data is available to the treating physician for later review through Physician App reporting functionality
App OS Requirement	Same as predicate	Windows 10/11 local application
Platform	Runs on user-provided PC	Runs on cybersecure, Balance-provided PC laptop

	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
App Log-in	Care-App specific Log-in  Splash Screen  Log-in screen	Log-in controlled through Windows
App Home Screen	Displays a list of patients treated by the logged-in physician and basic usage statistics downloaded from Balance Cloud Platform 	Waiting for a FSYX OPAP Pump to be connected through the USB cable 

	SUBJECT DEVICE	PRIMARY PREDICATE
	<p align="center">FSYX Ocular Pressure Adjusting Pump System</p>	<p align="center">FSYX Ocular Pressure Adjusting Pump System DEN230055</p>
<p align="center">App Programming</p>	<p>Consolidates the Device Programming functionality and Usage data in one screen</p> <p>A FSYX OPAP Pump can be programmed ONLY when PHYSICALLY connected to the PC through a USB-C cable.</p>  <p>Additionally:</p> <ul style="list-style-type: none"> • Usage data can be displayed even when a device is not connected (downloaded from Balance’s Cloud Platform) • More intuitive graphical display and navigation of usage data • Provides access to a screen displaying usage data in tabular form 	<p>Provides the Device Programming functionality and Usage data in two separate screens</p> <p>A FSYX OPAP Pump can be programmed ONLY when PHYSICALLY connected to the PC through a USB-C cable.</p>  

	SUBJECT DEVICE	PRIMARY PREDICATE
	FSYX Ocular Pressure Adjusting Pump System	FSYX Ocular Pressure Adjusting Pump System DEN230055
App Physician Data	<p>Implements a dedicated screen for the display of basic details of the logged-in physician.</p> 	Does not display any information relative to the treating physician.
Packaging	Same as predicate	Provided non-sterile in protective packaging
Design Life Pump: Battery : Goggles:	Same as predicate	5 years 500 Cycles 1 month

VII. Summary of Non-Clinical Testing

Based on the risk assessment, design control requirements, and the minimal changes to the subject device, the following verification and validation testing was performed:

- Device performance testing:
 - Pressure Limiting Functionality
 - Hardware Verification - OPAP 5G
 - System Verification - OPAP 5G
- Software verification and validation testing: Balance Ophthalmics developed and verified the software in accordance with a determination of “Enhanced Documentation” described in the FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and also per the IEC 62304 Medical Device Software - Software Life Cycle Processes standard.
- Cybersecurity assessment and documentation based on the FDA guidance “Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions”
- Electromagnetic compatibility (EMC) evaluation was conducted per IEC 60601-1 Medical electrical equipment – Part 1-2: General requirements for safety and essential

performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests.

- Electrical safety evaluation was conducted per IEC 60601-1 Medical electrical equipment – Part 1: General requirements for safety 1: collateral standard: Safety Requirements for Medical Electrical Systems.

Results of the non-clinical testing support a substantial equivalence determination. The FSYX™ Ocular Pressure Adjusting Pump System is substantially equivalent to its predicate device for the indications for use.

VIII. Conclusions

The FSYX™ Ocular Pressure Adjusting Pump System has the same intended use as the legally marketed predicate device identified in this premarket notification. The technological characteristics of the FSYX™ Ocular Pressure Adjusting Pump System differ from those of the predicate device only with respect to the over pressure limit feature, activation of a cellular module for unidirectional (i.e. from the device only) transmission of usage data to Balance's Cloud Platform, the use of the Care App on a user-provided Windows personal computer, user access to the Care App controlled by Balance's Cloud platform, and inclusion of basic PHI in Balance's Cloud Platform (i.e. patient names), but the differences do not raise new or different types of questions of safety or effectiveness. The results of the non-clinical performance testing demonstrate that the FSYX™ Ocular Pressure Adjusting Pump System functions as intended. The non-clinical performance testing demonstrates that the FSYX™ Ocular Pressure Adjusting Pump System is substantially equivalent to the predicate device.