January 06, 2022

Glaukos Corporation
Alex Bhaskarla
Senior Regulatory Affairs Associate
229 Avenida Fabricante
San Clemente, CA 92672

Re: K212797
Trade/Device Name: iPrime Viscodelivery System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRH
Dated: August 31, 2021
Received: September 2, 2021

Dear Alex Bhaskarla:

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 (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 located 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.

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 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 Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for Tieuvi Nguyen, Ph.D.
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212797

Device Name
iPRIME™ Viscodelivery System

Indications for Use *(Describe)*
The iPRIME™ Viscodelivery System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example HEALON® PRO from Johnson & Johnson Vision, Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery.

Type of Use *(Select one or both, as applicable)*

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510k Summary

510(k) Owner:	Glaukos Corporation 229 Avenida Fabricante San Clemente, California 92672 Telephone: 949-367-9600 Fax: 949-367-9984
Contact Person:	Alex Bhaskarla Senior Regulatory Affairs Associate Telephone: 949-481-0672 Fax: 949-367-9984
Date Prepared:	November 19, 2021
Device Trade Name:	iPRIME™ Viscodelivery System
Classification:	II
Classification Name:	Infusion Pump
Product Code:	MRH
Regulation Number:	CFR 880.5725
Predicate Device:	Sight Sciences VISCO360™ Viscosurgical System (K171905)

Device Description:

The iPRIME™ Viscodelivery System is a sterile, single-use ophthalmic surgical instrument for dispensing cohesive viscoelastic fluid (supplied separately, at point of use) during ophthalmic surgery.

The iPRIME™ Viscodelivery System is a delivery device for delivering viscoelastic fluid. The procedure is performed by a trained ophthalmic professional in a sterile surgical setting. The iPRIME device is filled by the user, at the point of use, with FDA approved commercially available cohesive viscoelastic fluid (e.g. HEALON® PRO, Amvisc® or PROVISC®; sold and supplied separately).

The iPRIME device consists of a handpiece which includes a reservoir, dispense trigger, cannula, slide button, rotatable hub, and microcatheter manufactured from medical grade materials. The slide button allows the user to adjust the microcatheter length. The dispense trigger dispenses the viscoelastic fluid. The rotatable hub allows the user to adjust the angle of the cannula in order to dispense viscoelastic fluid into other areas within the anterior chamber.

The iPRIME™ Viscodelivery System serves as dispensary means to deliver cohesive viscoelastic fluid. The OVD device containing the viscoelastic fluid is connected to the iPRIME luer fitting and viscoelastic is pumped into the iPRIME device.

After the device is fully primed and the microcatheter has been extended to the desired location, the user advances forward the dispense trigger delivering a small amount of viscoelastic fluid into the desired location within the anterior chamber of the eye.

Indication for Use:

The iPRIME™ Viscodelivery System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example HEALON® PRO from Johnson & Johnson Vision, Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery.

Comparison of Technological Characteristics with the Predicate Device

The technical characteristics of the iPRIME™ Viscodelivery System are substantially equivalent to the predicate device VISCO™ 360 Viscosurgical System (K171905). The iPRIME™ Viscodelivery System and predicate device are manually operated devices for the controlled delivery of small amounts of viscoelastic fluid and dispenses these fluids based on the principle of exchanging volumes much like a syringe. **Table 1** below compares the attributes of the iPRIME™ Viscodelivery System with the predicate device. The iPRIME™ Viscodelivery System is substantially equivalent to the predicate device as indicated below:

TABLE 1. SUBJECT AND PREDICATE DEVICE COMPARISON SUMMARY

Features	**Proposed Device** **iPRIME™ Viscodelivery System**	**Predicate Device** **VISCO™360 Viscosurgical System (K171905)**
Intended Use	User manually operated handheld device for delivery of viscoelastic fluid during ophthalmic surgery	Same
Indications for Use	The iPRIME™ Viscodelivery System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example HEALON® PRO from Johnson & Johnson Vision, Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery.	The Sight Sciences VISCO™360 Viscosurgical System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon™ or HealonGV™ from Abbot Medical Optics (AMO), Amvisc™ from Bausch & Lomb, or PROVISC™ from Alcon, during ophthalmic surgery.
Device Classification	Class II	Same
Product Code	MRH	Same
Dispensing Design	Passive volume dispensing syringe mechanism	Same
Dispensing Control	Manual forward slide of trigger to dispense viscoelastic fluid	Manual rotation of actuator wheel to dispense viscoelastic fluid
Materials	Medical grade stainless steel cannula and ABS molded plastic components	Same
Microcatheter Dimensions	Microcatheter (17mm max L, 200 microns OD	Microcatheter (21 mm L, 200 microns OD
Viscoelastic Fluid	2.7 µL of cohesive viscoelastic fluid (supplied separately) per activation of dispense trigger. No total volume limit	4.5 µL per delivery, 9 µL total volume dispensed
Target Anatomy	Anterior chamber of eye	Same

Summary of Non-clinical Data:

The iPRIME™ Viscodelivery System was subjected to biocompatibility, sterilization, package integrity, and performance tests to ensure its functionality is consistent with cohesive viscoelastic fluid infusion pumps.

The iPRIME device was subjected to the following functional and performance tests to ensure its stability over a three-month shelf life:

- Joint strength testing
- Microcatheter and cannula extension/retraction testing
- Priming/dispense volume testing
- Corrosion testing
- Human factors engineering evaluation

Biocompatibility testing was performed in accordance with ISO 10993-1: 2018 to ensure the direct and indirect patient contacting components are biocompatible:

- Cytotoxicity
- Sensitization
- Intracutaneous irritation
- Systemic toxicity

Package integrity testing was performed in order to ensure the sterile barrier is maintained throughout the three-month shelf life:

- Packaging visual inspection
- Packaging peel test
- Packaging bubble test

Acceptance criteria for testing was based on the ability to perform according to the intended use and predicate device characteristics. The tests results show that the iPRIME™ Viscodelivery System met all acceptance criteria and performs as intended.

Summary of Clinical Data:

Clinical data are not included in this submission and are not required. Substantial equivalence is based on technological comparison.

Conclusion from Data:

The iPRIME™ Viscodelivery System meets all product design requirements and applicable standards. The iPRIME™ Viscodelivery System has been shown to be substantially equivalent to the predicate device.