August 4, 2026

Sight Sciences, Inc.
Rachel Franco
Lead Regulatory Affairs Specialist
4040 Campbell Ave., Suite 100
Menlo Park, California 94025

Re: K253760
Trade/Device Name: OMNI Ultra Surgical System (1-110)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRH, HMZ
Dated: June 29, 2026
Received: June 30, 2026

Dear Rachel Franco:

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,

CLAUDINE H. KRAWCZYK -S

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.	K253760

Please provide the device trade name(s).

OMNI Ultra Surgical System (1-110)

Please provide your Indications for Use below.

The OMNI Ultra Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma.

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

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

510(k) SUMMARY

Submitter Information

510(k)Number: K253760

510(k) Owner: Sight Sciences, Inc.
4040 Campbell Ave., Suite 100
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Tel: (877) 266-1144

Contact Person: Rachel M. Franco
Lead Regulatory Affairs Specialist
4040 Campbell Ave., Suite 100
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Tel: 408-221-7376

Date Prepared: July 28, 2026

Device Name and Classification

TRADE NAME:	OMNI Ultra Surgical System
COMMON NAME:	Ophthalmic Infusion Pump
CLASSIFICATION NAME:	Infusion pump
REGULATION NUMBER:	21 CFR 880.5725
DEVICE CLASSIFICATION:	Class II
PRODUCT CODE:	MRH
DEVICE	Pump, infusion, ophthalmic
ASSOCIATED PRODUCT CODE	HMZ
DEVICE	trabeculotome

Predicate Device

Device Name: OMNI Surgical System
510(k) Holder: Sight Sciences, Inc.
510(k) Number: K232214
Clearance Date: August 25, 2023

Indications for Use

The OMNI® Ultra Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma.

Device Description

The Sight Sciences OMNI Ultra Surgical System is a handheld, manually operated device used by ophthalmologists to access, microcatheterize, and viscodilate Schlemm's canal ("canaloplasty") and to re-access Schlemm's canal and cut trabecular meshwork tissue ("trabeculotomy").The OMNI Ultra Surgical System is provided sterile and disposed after single-patient use. The device is fabricated from biocompatible materials standard to the medical device industry. Each OMNI Ultra device dispenses fluid on the principle of exchanging volumes much like a syringe and is designed to function with commercially available cohesive viscoelastic fluids (also known as ophthalmic viscosurgical device, or "OVD").

The OMNI Ultra device includes a stainless-steel cannula, polymeric microcatheter, removable priming lock, internal reservoir, a Luer fitting for direct connection with an OVD cartridge to prime the internal reservoir, and two advancement wheels. The stainless-steel cannula has a curved shape with a beveled tip for entry through the trabecular meshwork into Schlemm's canal. A single advancement wheel is located on each side of the handle. This allows the OMNI Ultra device to be used in either eye (OD or OS) and in either hand of the surgeon (left or right), by turning the device 180 degrees along its vertical axis. These wheels are used to advance and retract the microcatheter. To perform the combined and sequential canaloplasty/trabeculotomy procedures, the canaloplasty is performed first, followed by trabeculotomy. The subject OMNI Ultra Surgical System device dispense characteristics are described in **Table 1** below.

Table 1 OMNI Ultra Surgical System device dispense characteristics

Catalog Number	Description	Volume OVD Dispense on Advance	Volume OVD Dispense on Retraction
1-110	OMNI Ultra Surgical System	6 µl	15 µl

Comparison of Technological Characteristics with the Predicate

The primary predicate in this 510(k) submission is the OMNI Surgical System described in K232214. The OMNI Ultra Surgical System has the same intended use, indications for use, and similar technological characteristics as the predicate OMNI device. The proposed OMNI Ultra Surgical System updates aim to enhance the user experience while maintaining the same overall device performance with modifications limited to handle length, microcatheter travel length during canaloplasty, and dual OVD dispensing (on advancement and retraction) with the total volume dispensed equivalent to that of the predicate device (21 µl).

OMNI Ultra Surgical System Device updates do not significantly affect how the device is used, no new significant risks were identified with the changes, no unintended consequences of the changes were identified, and the changes did not significantly impact the safety or effectiveness of the device. A comparison of the technological characteristics between the subject OMNI Ultra Surgical System compared with the predicate OMNI Surgical System device is shown in **Table 2** below.

Table 2 Comparison of Technological Characteristics with the Predicate Device

Characteristic	OMNI Ultra Surgical System SUBJECT DEVICE	OMNI Surgical System PREDICATE DEVICE (K232214)
Intended Use	Ophthalmic surgical tool for delivery of controlled amounts of viscoelastic fluid into the anterior segment and used to cut trabecular meshwork when a trabeculotomy is indicated	Ophthalmic surgical tool for delivery of controlled amounts of viscoelastic fluid into the anterior segment and used to cut trabecular meshwork when a trabeculotomy is indicated
Indications for Use	The OMNI® Ultra Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma.	The OMNI® Ultra Surgical System is indicated for canaloplasty (microcatheterization and transluminal viscodilation of Schlemm's canal) followed by trabeculotomy (cutting of trabecular meshwork) to reduce intraocular pressure in adult patients with primary open-angle glaucoma.
Target Anatomy	Schlemm's Canal and Trabecular Meshwork	Schlemm's Canal and Trabecular Meshwork
Operating Principle	Manual	Manual
Dispensing Control	After priming, viscoelastic dispensing control occurs through manual rotation of either advancement wheel at the distal end of the device	After priming, viscoelastic dispensing control occurs through manual rotation of either advancement wheel at the distal end of the device
Dispensing Mechanism	Internal reservoir with plunger tube and AD rod (syringe-like volume exchange).	Internal reservoir with plunger tube (syringe-like volume exchange).
Viscoelastic Fluid (OVD) and Priming Method	Cohesive viscoelastic fluid (OVD or ophthalmic viscosurgical device) is supplied separately. Viscoelastic loaded into device (primed) prior to use by attaching OVD cartridge directly to Luer fitting on proximal end of OMNI device handle	Cohesive viscoelastic fluid (OVD or ophthalmic viscosurgical device) is supplied separately. Viscoelastic loaded into device (primed) prior to use by attaching OVD cartridge directly to Luer fitting on proximal end of OMNI device handle
OVD Volume Dispensed	Total 21 µL: 6 ± 3 µL during advancement and 15 ± 3 µL during retraction	21 ± 3µL – 10.5 µL/each during the first two retractions
Materials	Medical grade materials, including ABS, polycarbonate, stainless steel, silicone, parylene coating, cyanoacrylate, acrylated urethane, polyimide Microcatheter material: polyamide (Nylon) with laser markings and additives	Medical grade materials, including ABS, polycarbonate, stainless steel, silicone, parylene coating, cyanoacrylate, acrylated urethane, polyimide Microcatheter material: polyimide (Nylon)
User Interface	Handheld	Handheld
Microcatheter length	35 mm	20 mm
Microcatheter Shaft Outer Diameter	200 microns	200 microns

Characteristic	OMNI Ultra Surgical System SUBJECT DEVICE	OMNI Surgical System PREDICATE DEVICE (K232214)
Microcatheter Tip Outer Diameter Range	0.0095 to 0.0115 inches	0.0090 to 0.0110 inches
Sterile and Single Use	Provided sterile. Single patient use	Provided sterile. Single patient use
Sterilization Method	Gamma radiation	Gamma radiation
Sterility Assurance Level	10^{-6}	10^{-6}
Packaging	Thermoformed plastic tray with heat-sealed Tyvek lid	Thermoformed plastic tray with heat-sealed Tyvek lid

Risk Analysis

The risk management process at Sight Sciences complies with ISO 14971:2019 *"Medical devices -- Application of risk management to medical devices."* As required by this standard, risk analyses are conducted according to defined procedures, using experienced, qualified personnel from multiple functions throughout the organization with prior experience in risk assessment. All the identified hazards were mitigated to an acceptable level of risk. The potential benefits to patients outweigh the low residual risk, taking into consideration the indications for use of the OMNI Ultra Surgical System.

Performance Data – Bench Testing

The descriptive characteristics of the OMNI Ultra Surgical System are well-defined and adequate to ensure equivalence to the predicate device. Additionally, the following performance testing and inspections were conducted on the OMNI Ultra device: dimensional and visual inspections, visual inspection of labeling and component inspections, mechanical testing of joint strength and actuation force, simulated use testing, sterilization validation, packaging and shelf-life testing, biocompatibility testing, bacterial endotoxin testing, and comparative human cadaver eye performance testing. Acceptance criteria were based on design inputs including predicate OMNI performance, relevant standards, and where applicable, comparison to the predicate device performance. Testing demonstrated that the OMNI Ultra device performs as intended and meets defined specifications and functions as intended and demonstrates that the OMNI Ultra Surgical System is substantially equivalent to the legally marketed OMNI Surgical System predicate device cleared under K232214.

Conclusions Drawn from Testing

Based on the testing conducted on the physically identical OMNI Ultra Surgical System, the Sight Sciences modified OMNI Ultra Surgical System has complied with applicable standards and met all product design requirements. The subject device shares the same principle of operation, intended use, indications for use, and many of the same key technological characteristics as the predicate device. Performance testing and inspections conducted on the OMNI Ultra device included: dimensional and visual inspections, visual inspection of labeling and component inspections, mechanical testing of joint strength and actuation force, simulated use testing, sterilization validation, packaging and shelf-life testing, biocompatibility testing, bacterial endotoxin testing, and comparative human cadaver eye performance testing. This testing demonstrated that the OMNI Ultra device performs as intended, meets defined specifications, and functions as intended and demonstrates that the OMNI Ultra Surgical System is substantially equivalent to the legally marketed OMNI Surgical System predicate device cleared under K232214. Acceptance criteria were based on design inputs including predicate OMNI performance, relevant standards, and where applicable, comparison to the predicate device performance. Therefore, the OMNI Ultra Surgical System is substantially equivalent to the legally marketed OMNI Surgical System predicate device cleared under K232214.