Sight Sciences, Inc.
Mr. Edward Sinclair
Vice President, Regulatory Affairs
4040 Campbell Ave., Suite 100
Menlo Park, CA 94025

Re: K201953
Trade/Device Name: OMNI PLUS Surgical System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: Class II
Product Code: MRH, HMZ
Dated: July 13, 2020
Received: July 14, 2020

Dear Mr. Sinclair:

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 LT Charles Chiang
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

510(k) SUMMARY

Submitter Information

510(k) Owner:	Sight Sciences, Inc. 4040 Campbell Ave., Suite 100 Menlo Park, CA 94025 Tel: (877) 266-1144
Contact Person:	Edward J. Sinclair Vice President, Regulatory Affairs 4040 Campbell Ave., Suite 100 Menlo Park, CA 94025 Tel: 650-218-9149

Date Prepared: June 23, 2020

Device Name and Classification

Trade Name:	OMNI® PLUS Surgical System
Common Name:	Ophthalmic Infusion Pump
Classification Name:	Infusion Pump
Regulation Number:	21 CFR 880.5725
Device Classification:	Class II
Primary Product Code:	MRH
Secondary Product Code:	HMZ

Predicate Device

Device Name:	OMNI® Surgical System
510(k) Holder:	Sight Sciences, Inc.
510(k) Number:	K173332
Clearance Date:	December 21, 2017

Intended Use

The OMNI® PLUS Surgical System is an ophthalmic surgical tool for the delivery of controlled amounts of viscoelastic fluid into the anterior segment and the cutting of trabecular meshwork when a trabeculotomy is indicated.

Indications for Use

The OMNI® PLUS Surgical System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon® PRO or Healon GV® PRO from Johnson & Johnson Vision,

Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures.

Device Description

The OMNI PLUS Surgical System is a sterile, single use, manually operated instrument used by ophthalmologists to deliver small, controlled amounts of viscoelastic fluid into the anterior segment of the eye during ophthalmic surgery and cut trabecular meshwork tissue during trabeculotomy procedures. The OMNI PLUS device is provided sterile and disposed after single-patient use. The device is fabricated from biocompatible materials standard to the medical device industry. The OMNI PLUS Surgical System dispenses fluid on the principle of exchanging volumes much like a syringe and are designed to function with commercially available cohesive viscoelastic fluids (also known as an *ophthalmic viscosurgical device*, or "OVD") that are commercially available from companies such as Johnson & Johnson, Bausch & Lomb, and Alcon.

The OMNI PLUS device includes a stainless-steel cannula, polymeric microcatheter, removable priming lock, internal reservoir and plunger tube, a Luer fitting for direct connection with an OVD cartridge to prime the internal reservoir, and two advancement wheels. A single advancement wheel is located on each side of the handle. This allows the OMNI PLUS 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.

The microcatheter can be advanced/retracted up to 20 mm per cycle by manually rotating either advancement wheel. The microcatheter can be fully advanced/retracted multiple times, however, viscoelastic fluid can only be dispensed during the first two advancement/retraction cycles. When the OMNI PLUS device is being used to deliver viscoelastic fluid, retraction of the microcatheter causes a plunger tube to advance into the viscoelastic fluid reservoir thereby automatically dispensing viscoelastic fluid as the microcatheter is being retracted back into the stainless-steel cannula.

When the OMNI PLUS Surgical System is used to perform a trabeculotomy procedure, the beveled tip of the curved stainless-steel cannula is used to enter Schlemm's canal through the trabecular meshwork. The polymeric microcatheter is advanced into Schlemm's canal up to 180 degrees (one hemisphere) by rotating the advancement wheel forward until the wheel stops (about 20 mm). With the microcatheter resting in the canal, the cannula is removed from the corneal incision and out of the eye causing the microcatheter to cut through the trabecular meshwork. This process can be repeated in the second Schlemm's hemisphere.

The OMNI PLUS Surgical System is an additional model based on the current OMNI Surgical System design; OMNI PLUS is designed to dispense a nominal volume of 21 microliters of viscoelastic fluid.

Comparison of Technological Characteristics with the Predicate Device

The technical features of the OMNI PLUS Surgical System are substantially equivalent to the OMNI Surgical System predicate device (cleared by FDA in K173332 on December 21, 2017). The OMNI

PLUS Surgical System is an additional model based on the OMNI Surgical System design. The primary functional difference between the predicate device and subject device is the volume of viscoelastic fluid that can be delivered during use. The predicate OMNI Surgical System delivers a nominal volume of approximately 9 microliters of viscoelastic fluid, whereas the subject OMNI PLUS design can deliver a nominal volume of approximately 21 microliters of viscoelastic fluid. In order to deliver the additional viscoelastic fluid, three internal components, consisting of the reservoir, plunger tube and distal O-ring, have modified dimensions to contain and dispense additional viscoelastic fluid in the OMNI PLUS device. Other changes were made to improve the aesthetics, ergonomics and manufacturability of the device. These include the handle shape and materials, reduced number of advancement wheels, addition of a proximal Luer fitting to aid priming and a packaging tray with a heat-sealed Tyvek lid. Other minor changes are included in the technological attributes comparison between the OMNI PLUS Surgical System (subject device) with the OMNI Surgical System (predicate device) in ***Table 1*** below.

Table 1: Technological Characteristics Comparison
OMNI PLUS Surgical System and Predicate Device

Characteristic	OMNI PLUS Surgical System SUBJECT DEVICE	OMNI Surgical System (K173332) PREDICATE DEVICE
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 indications were updated to reflect a change in manufacturer of the Healon viscoelastic fluids from Abbott Medical Optics to Johnson & Johnson, as well as to add the OMNI PLUS Surgical System as follows: The OMNI PLUS Surgical System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon® PRO or Healon GV® PRO from Johnson & Johnson Vision, Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures	The OMNI Surgical System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon® or Healon GV® from Abbott Medical Optics (AMO), Amvisc® from Bausch & Lomb, or PROVISC® from Alcon, during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures
Regulation	880.5725 (Infusion Pump)	880.5725 (Infusion Pump)
Device Class	Class II	Class II
Product Code	Primary: MRH Secondary: HMZ	Primary: MRH Secondary: HMZ
Prescription Status	Prescription use only	Prescription use only
Target Anatomy	Anterior Segment including Schlemm's Canal/Trabecular Meshwork	Anterior Segment including Schlemm's Canal/Trabecular Meshwork
Operating Principle	Manual	Manual

Characteristic	OMNI PLUS Surgical System SUBJECT DEVICE	OMNI Surgical System (K173332) PREDICATE DEVICE
Design/ Mechanism of Action	• Flexible microcatheter with rounded, atraumatic tip for dispensing of viscoelastic • Proximal handle – changed to ovoid shape • Handle has internal viscoelastic reservoir and plunger tube with dimensional changes to allow dispensing of additional viscoelastic • Two advancement wheels (finger wheels) for advancing and retracting microcatheter up to 20mm using a rack and pinion mechanism • Tactile and audible clicks indicate precise advancement • Viscoelastic dispensed during retraction of first two cycles after priming with viscoelastic fluid • Flexible microcatheter introduced into Schlemm's canal and pulled through to cut trabecular meshwork	• Flexible microcatheter with rounded, atraumatic tip for dispensing of viscoelastic • Proximal handle – rectangular shape • Handle has internal viscoelastic reservoir and plunger tube • Four advancement wheels (finger wheels) for advancing and retracting microcatheter up to 20mm using a rack and pinion mechanism • Tactile and audible clicks indicate precise advancement • Viscoelastic dispensed during retraction of first two cycles after priming with viscoelastic fluid • Flexible microcatheter introduced into Schlemm's canal and pulled through to cut trabecular meshwork
Dispensing Control	After priming, viscoelastic fluid dispensing control occurs through manual rotation of the advancement wheels at the distal end of the device. The ovoid shape of the handle allows a single advancement wheel on each side of the handle while maintaining the ability for ambidextrous use in either patient eye. Synchronization of the advancement wheels and microcatheter movement was achieved for ease of use by adding a gear in the rack and pinion mechanism.	After priming, viscoelastic fluid dispensing control occurs through manual rotation of the advancement wheels at the distal end of the device. The rectangular shape of the handle required two advancement wheels on each side of the handle for ambidextrous use in either patient eye
Dispensing Mechanism	Internal reservoir with plunger tube (syringe-like volume exchange). Three components consisting of the Reservoir, Plunger Tube and Distal O-Ring have modified dimensions to contain and dispense larger volume of viscoelastic fluid (OVD)	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 to a supplied nozzle and advancing into proximal end of OMNI device handle
OVD Volume Dispensed	21 ± 3 µL (10.5 µL on first microcatheter retraction cycle and 10.5 µL on the second cycle)	9 ± 3 µL (4.5 µL on first microcatheter retraction cycle and 4.5 µL on the second cycle)

Characteristic	OMNI PLUS Surgical System SUBJECT DEVICE	OMNI Surgical System (K173332) PREDICATE DEVICE
Materials	Medical grade materials, including ABS, polycarbonate, stainless steel, silicone, parylene coating, cyanoacrylate, acrylated urethane, polyimide. Minor changes were made to the materials in the handle, reservoir, Luer fitting and a new bonding adhesive was used	Medical grade materials, including ABS, polycarbonate, stainless steel, silicone, parylene coating, cyanoacrylate, acrylated urethane, polyimide
User Interface	Handheld	Handheld
Microcatheter Shaft Outer Diameter	200 microns	200 microns
Microcatheter Tip Outer Diameter Range	0.0090 to 0.0110 inches. The lower specification limit was reduced by 0.0005 inches	0.0095 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	Tyvek pouch with a polymer tray card
Shelf Life	13 months	6 months

Risk Management

The risk management process at Sight Sciences complies with ISO 14971:2012 *"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.

Risk management activities were first documented in a Risk Management Plan. This plan specified the risk management activities to be conducted based on the changes to the cleared OMNI Surgical System that resulted in the OMNI PLUS Surgical System design. The following activities were completed:

- The Clinical Hazard Analysis for the OMNI Surgical System changes and the OMNI PLUS Surgical System was re-assessed by qualified personnel with respect to all changes.
- All identified hazards associated with the OMNI devices were evaluated and recorded along with potential harm and effects resulting from the hazard and the severity ranking of each hazard in Failure Modes Effect Analyses (FMEAs).
- Potential hazards were mitigated through the device design and manufacturing processes and any mitigations were subsequently verified.

All the identified hazards were mitigated to an acceptable level of risk. The potential benefits to patients outweigh the low residual risk of the design changes and taking into consideration the indications for use of the OMNI devices.

Performance Data – Bench Testing

Non-clinical bench testing included design verification and functional product testing, sterilization validation, packaging and shelf life testing, biocompatibility testing, bacterial endotoxin testing and simulated use (usability) testing in a bench model. Results of the nonclinical testing demonstrate that the OMNI PLUS Surgical System meets the defined specifications and functioned as intended.

Design Verification and Functional Product Testing

Design verification testing was performed to demonstrate the OMNI PLUS Surgical System device meets the performance requirements described in the Product Specification after the following conditioning: worst-case dosage sterilization cycle, extreme conditions environmental exposure, simulated transit and accelerated and real-time aging. After conditioning and accelerated aging, test samples were subjected to a variety of tests including mechanical integrity assessment, sterile barrier packaging testing, physical requirements, product inspections and specification verifications. The results establish that the OMNI PLUS Surgical System functioned as intended and complies with the applicable requirements.

Sterilization Validation

The OMNI PLUS Surgical System was adopted into the sterilization process that was validated for the predicate OMNI device in K173332. Sterilization is performed by the same approved contractor. The rationale for adoption was based on similarities in mass and product-related variables that affect bioburden. In addition to a written justification for adoption of the OMNI PLUS Surgical System, representative device samples were tested for bioburden and subjected to a verification dose experiment as a demonstration of process effectiveness. The tested units were found to be sterile after processing with the sub-lethal dose, confirming that the product may be labeled “Sterile” per ANSI/AAMI/ISO 11137-2:2013.

Packaging and Shelf Life Testing

The OMNI PLUS Surgical System is currently validated for total shelf life of 13 months. The device packaging is labeled with an expiration date of 12 months, providing a one-month safety factor. The shelf life study evaluated the functional performance of the OMNI PLUS Surgical System, as well as the packaging integrity of the tray sealed with the Tyvek lid after test samples were subjected to worst-case dosage sterilization cycle, extreme conditions environmental exposure, simulated transit conditioning, and real-time aging. After conditioning and real-time aging for a minimum of 13 months, OMNI samples were subjected to a variety of tests related to shelf life including visual verification of packaging, labeling and device integrity, sterile barrier packaging testing, and functional performance testing.

Biocompatibility and Bacterial Endotoxin Testing

Biocompatibility of the OMNI PLUS Surgical System was demonstrated through testing in accordance with ISO 10993- 1:2009/(R)2013 “*Biological Evaluation of Medical Devices – Part 1:*

Evaluation and testing within a risk management process." Testing was performed by an approved contract laboratory on all components that have direct or indirect contact with the patient. Test results demonstrated that the device materials have an acceptable biocompatibility profile and met the requirements of the ISO standard. Additionally, OMNI PLUS devices were tested for bacterial endotoxin according to USP <85>:2011 "*Bacterial Endotoxin Test*" and ANSI/AAMI ST72:2011/(R)2016 "Bacterial endotoxins – Test methodologies, routine monitoring, and alternatives to batch testing." Test results demonstrated that the samples do not have an unacceptable level of bacterial endotoxin and met the endotoxin limit requirement of ≤0.2 EU/device.

Conclusions

The Sight Sciences OMNI PLUS Surgical System meets all product design requirements and applicable standards as the predicate OMNI Surgical System. The subject device shares the same principle of operation, intended use/indications and many of same key technological characteristics as the predicate device. Differences in technological characteristics were evaluated using the same recognized consensus standards and scientific methods used to clear the predicate device in K173332. The conclusions drawn from the non-clinical bench performance tests demonstrate that the OMNI PLUS Surgical System meets the defined specifications and performs as intended.

The OMNI PLUS Surgical System is substantially equivalent to the legally-marketed OMNI Surgical System predicate device cleared under 510(k) K173332.