August 25, 2023

Sight Sciences, Inc.
Ranjani Madhavan
Senior Regulatory Affairs Specialist
4040 Campbell Ave., Suite 100
Menlo Park, California 94025

Re: K232214
Trade/Device Name: OMNI Surgical System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRH
Dated: July 25, 2023
Received: July 26, 2023

Dear Ranjani Madhavan:

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,

Claudine H. Krawczyk -S

Claudine Krawczyk
Acting 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

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)*

K232214

Device Name
OMNI Surgical System

Indications for Use *(Describe)*

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

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.

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510(k) SUMMARY

Submitter Information

510(k) Owner: Sight Sciences, Inc.
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Tel: (877) 266-1144

Contact Person: Ranjani Madhavan
Senior Regulatory Affairs specialist
4040 Campbell Ave., Suite 100
Menlo Park, CA 94025
Tel: 818-585-1124

Date Prepared: August 25, 2023

Device Name and Classification

Trade Name:	OMNI® 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:	K202678
Clearance Date:	March 1, 2021

Reference Device

Device Name	OMNI® PLUS Surgical System
510(k) Holder	Sight Sciences, Inc.
510(k) Number	K201953
Clearance Date	August 11, 2020

Reference Device

Device Name	ISCIENCE Interventional Ophthalmic Microcatheter*
510(k) Holder	ISCIENCE Interventional#
510(k) Number	K080067
Clearance Date	July 18, 2008

Note: *commercially available now as iTrack™
#IScience Interventional is now Nova Eye Medical

Intended Use

The OMNI® 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® 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 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 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 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 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. 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 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 as explained in further detail below.

Performing Canaloplasty First: the microcatheter is advanced into Schlemm's canal up to 180 degrees (one hemisphere) by rotating the advancement wheel forward until the wheel stops (about 20mm). When the device is being used to deliver viscoelastic fluid, retraction of the microcatheter causes the plunger tube to advance into the viscoelastic fluid reservoir thereby automatically dispensing viscoelastic fluid along the length of Schlemm's canal and collector channels. The microcatheter can be advanced/retracted up to 20 mm per cycle by manually rotating the 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 in order to dispense viscoelastic fluid along each hemisphere of Schlemm's canal. Thus, the OMNI Surgical System device is designed to be used twice within Schlemm's canal to deliver a controlled volume of viscoelastic fluid along the first 180 degrees of the canal, followed by a second delivery of viscoelastic fluid along the other 180 degrees. The modified OMNI Surgical System (subject device) delivers a total viscoelastic fluid volume of 21 microliters throughout Schlemm's canal (approximately 10.5 microliters for each of the first two advancement/retraction cycles).

Performing Trabeculotomy Second: the beveled tip of the curved stainless-steel cannula is re-positioned into the same Schlemm's canal location after finishing canaloplasty. The polymeric microcatheter is re-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 modified OMNI Surgical System (catalog number 1-106) has the identical indications for use as the current OMNI Surgical System and similar design; the modified OMNI has the identical design as the OMNI PLUS Surgical System reference device which includes the ability to dispense a nominal volume of 21 microliters of viscoelastic fluid.

Comparison of Technological Characteristics with the Predicate Device

The modified OMNI Surgical System (catalog number 1-106) has the same indications for use and similar technological characteristics as the OMNI Surgical System (cleared by FDA in K202678 on March 1, 2021). The primary functional difference between the predicate device and subject device is the volume of viscoelastic fluid that can be delivered during use. The technical features of the modified OMNI Surgical System are substantially equivalent (identical including the volume of viscoeleastic fluid that can be delivered during use) to the OMNI PLUS Surgical System reference device (cleared by FDA in K201953 on August 11, 2020). The predicate OMNI Surgical System delivers a nominal volume of approximately 11 microliters of viscoelastic fluid, whereas the subject OMNI design can deliver a nominal volume of approximately 21 microliters of viscoelastic fluid (this volume is identical to the volume that can be delivered by the reference device OMNI PLUS). 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 as compared to the predicate OMNI device. Additionally, the technical features of the subject OMNI surgical system are similar, but not identical to the commercially available interventional ophthalmic microcatheter-iTrack reference device (K080067, formerly the iScience Interventional Canaloplasty Microcatheter). The subject OMNI surgical system and the iTrack device are both manually operated devices that utilize a microcatheter to access the Schlemm's canal and deliver viscoelastic fluid. Fluid is dispensed from each system on the principle of exchanging volumes much like a syringe. The iTrack device dispenses 2.25 microliters of viscoelastic fluid per click of the visco injector (without any limitation on the amount of OVD that can be delivered). The iTrack device serves as a reference device to support the scientific method used to assess substantial equivalence of the subject device that delivers a nominal 21 microliters to lower IOP in glaucoma patients. The iTrack device is used in the same anatomical location as the OMNI device and is intended for use to perform canaloplasty to lower IOP in glaucoma patients, which is similar to the intended use proposed for the OMNI device. The technological attributes comparison between the modified OMNI Surgical System (subject device) with the OMNI Surgical system (predicate device), OMNI Plus Surgical System (reference Device) and the iTrack (reference device) are presented in Table 1 below.

Table 1: Technological Characteristics Comparison
Modified OMNI Surgical System and Predicate Devices

Characteristic	OMNI Surgical System (Catalog #1-106) SUBJECT DEVICE	OMNI Surgical System Predicate (K202678)	OMNI PLUS Surgical System Reference Device (K201953)	ISCIENCE INTERVENTIONAL OPHTHALMIC MICROCATHETER Reference Device (K080067)
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	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	Delivery of controlled amounts of Viscoelastic fluid during ophthalmic surgery
Indications for Use	The OMNI® Surgical System is indicated for canaloplasty (micro-catheterization 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® Surgical System is indicated for canaloplasty (micro-catheterization 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 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 iScience Interventional Canaloplasty Microcatheter is indicated for fluid infusion and aspiration during surgery. The iScience Interventional Canaloplasty Microcatheter is indicated for catheterization and viscodilation of Schlemm's canal to reduce intraocular pressure in adult patients with open angle glaucoma
Regulation	880.5725 (Infusion Pump)	880.5725 (Infusion Pump)	Primary: 880.5725 (Infusion Pump) Secondary: 886.4350 (Manual ophthalmic surgical instrument)	886.4350 (Manual ophthalmic surgical instrument) 876.1500 (Endoscope and accessories)
Device Class	Class II	Class II	Class II	Class II
Product Code	Primary: MRH (Ophthalmic Infusion Pump) Secondary: HMZ (Trabeculotome)	Primary: MRH (Ophthalmic Infusion Pump) Secondary: HMZ (Trabeculotome)	Primary: MRH (Ophthalmic Infusion Pump) Secondary: HMZ (Trabeculotome)	Primary: MPA (Endoscope) Secondary: HMX (Manual Ophthalmic Surgical Instrument)
Prescription Status	Prescription use only	Prescription use only	Prescription use only	Prescription use only
Target Anatomy	Schlemm's Canal and Trabecular Meshwork	Schlemm's Canal and Trabecular Meshwork	Anterior Segment including Schlemm's Canal/Trabecular Meshwork	Schlemm's Canal and Trabecular Meshwork
Operating Principle	Manual	Manual	Manual	Manual

Characteristic	OMNI Surgical System (Catalog #1-106) SUBJECT DEVICE	OMNI Surgical System Predicate (K202678)	OMNI PLUS Surgical System Reference Device (K201953)	ISCIENCE INTERVENTIONAL OPHTHALMIC MICROCATHETER Reference Device (K080067)
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 – 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 – 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 for dispensation of viscoelastic fluid • Microcatheter has a round, bolus, atraumatic tip • The Microcatheter is connected to the ViscoInjector™ and primed with viscoelastic fluid from a cartridge retained with the ViscoInjector. • The Microcatheter is connected to a powered iLumin™ Fiberoptic Illuminator which illuminates the Microcatheter tip. • The surgeon directs the microcatheter using micro forceps through the surgical incision into the ostium of the Schlemm's canal. • The Microcatheter can access 360° of the Schlemm's canal in one pass. • As surgeon withdraws the microcatheter from the Schlemm's canal, viscoelastic fluid is delivered into the canal by the surgeon by manual clockwise rotation of the knob on ViscoInjector. • Clicks on the ViscoInjector™ tactilely indicate precise delivery of viscoelastic fluid.
Dispensing Control	After priming, viscoelastic fluid dispensing control occurs through manual rotation of the advancement wheels at the distal end of the device. The	After priming, viscoelastic fluid dispensing control occurs through manual rotation of the advancement wheels at the distal end of the device. The ovoid	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	Rotational action via a knob on the ViscoInjector to dispense viscoelastic fluid

Characteristic	OMNI Surgical System (Catalog #1-106) SUBJECT DEVICE	OMNI Surgical System Predicate (K202678)	OMNI PLUS Surgical System Reference Device (K201953)	ISCIENCE INTERVENTIONAL OPHTHALMIC MICROCATHETER Reference Device (K080067)
	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.	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.	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.	
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).	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)	OVD cartridge attaches to the device, inside the ViscoInjector (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	Cohesive viscoelastic fluid (OVD or ophthalmic viscosurgical device) is s upplied 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 oph thalmic viscosurgical device) is supplied separately. OVD cartridge attaches to the device inside the Ellex ViscoInjector
OVD Volume Dispensed	21 ± 3 µL (10.5 µL on first microcatheter retraction cycle and 10.5 µL on the second cycle)	11 µL	21 ± 3 µL (10.5 µL on first microcatheter retraction cycle and 10.5 µL on the second cycle)	2.25µL per click of the Viscoinjector (no limit of total volume that can be delivered)
Materials	Medical grade materials, including ABS, polycarbonate, stainless steel,	Medical grade materials, including ABS, polycarbonate, stainless steel, silicone, parylene	Medical grade materials, including ABS, polycarbonate, stainless steel, silicone, parylene coating,	Microcatheter – polyimide tubing and an outer sheath of polyethylene

Characteristic	OMNI Surgical System (Catalog #1-106) SUBJECT DEVICE	OMNI Surgical System Predicate (K202678)	OMNI PLUS Surgical System Reference Device (K201953)	ISCIENCE INTERVENTIONAL OPHTHALMIC MICROCATHETER Reference Device (K080067)
	silicone, parylene coating, cyanoacrylate, acrylated urethane, polyimide.	coating, cyanoacrylate, acrylated urethane, polyimide.	cyanoacrylate, acrylated urethane, polyimide.	terephthalate (PET) shrink tubing, with a lubricious coating
User Interface	Handheld	Handheld	Handheld	Handheld
Microcatheter Shaft Outer Diameter	200 microns	200 microns	200 microns	200 microns
Microcatheter Tip Outer Diameter Range	0.0090 to 0.0110 inches	0.0090 to 0.0110 inches	0.0090 to 0.0110 inches	0.0098 inches
Sterile and Single Use	Provided sterile. Single patient use	Provided sterile. Single patient use	Provided sterile. Single patient use	Provided sterile. Single patient use
Sterilization Method	Gamma radiation	Gamma radiation	Gamma radiation	Gamma radiation
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	10^{-6}
Packaging	Thermoformed plastic tray with heat-sealed Tyvek lid	Thermoformed plastic tray with heat-sealed Tyvek lid	Thermoformed plastic tray with heat-sealed Tyvek lid	Tray inside a sealed pouch
Shelf Life	37 Months	13 Months	13 months	Unknown

Risk Management

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.
Per the product development plan for this modified OMNI Surgical system, the following risk management activities were conducted:

- Per the plan, the Risk Management Report was reviewed, and no new risks were identified. The Risk Management Report was updated to reflect this new OMNI catalog/part number and to add reference to the supporting clinical study reports. Reference to the clinical assessment associated with Larger (21 uL) OVD Delivery was also added to the risk management report.
- All identified hazards associated with the OMNI devices were evaluated and no updates to the FMEAs were required.

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

Performance Data – Bench Testing

The verification and validation activities were previously performed for the OMNI PLUS Surgical System reference device (cleared in K201953 on August 11, 2020) which is physically identical to the modified OMNI Surgical System (catalog # 1-106) and did not need to be repeated for this OMNI Surgical System (catalog number 1-106) device. The non-clinical bench testing of the OMNI PLUS device 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.

Additionally, the shelf life was extended to up to 37 months and testing was conducted by subjecting devices to worst-case radiation sterilization dosage exposure and simulated aging in a controlled environment. Subsequently, the devices underwent visual inspection , sterile barrier packaging testing, and functional performance testing.

Results of the nonclinical testing are directly applicable to the modified OMNI Surgical System and demonstrate that the modified OMNI Surgical System meets the defined specifications and functions as intended.

Conclusions

Based on the testing conducted on the physically identical OMNI PLUS Surgical System, the Sight Sciences modified OMNI Surgical System has met all product design requirements and applicable standards as the predicate OMNI and the reference OMNI PLUS Surgical System. 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. The conclusions drawn from the

non-clinical bench performance tests demonstrate that the modified OMNI Surgical System meets the defined specifications and performs as intended. Based on the changes made as compared to the cleared predicate and the evaluation of the effect on the clinical outcomes from the change to increase the delivery volume of OVD provided in the clinical assessment comparison of the predicate OMNI device and reference iTrack device, it was appropriate to leverage the clinical data used in support of the cleared predicate device. Therefore, the OMNI Surgical System is substantially equivalent to the legally marketed OMNI Surgical System predicate device cleared under K202678.