December 21, 2017

Sight Sciences, Inc.
Anne-Marie Ripley
VP, Clinical & Regulatory Affairs
3000 Sand Hill Road
Building 3, Suite 105
Menlo Park, CA 94025

Re: K173332
Trade/Device Name: OMNI Surgical System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRH, HMZ
Dated: October 19, 2017
Received: October 23, 2017

Dear Anne-Marie Ripley:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Bradley S. Cunningham -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173332

Device Name
OMNI™ Surgical System

Indications for Use *(Describe)*
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.

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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1. 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT

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OFFICIAL CORRESPONDENT

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DATE SUMMARY WAS PREPARED: December 21, 2017

TRADE NAME:	OMNI™ Surgical System	
CLASSIFICATION NAMES	Infusion Pump	Manual Ophthalmic Instrument
REGULATION NUMBERS	21 CFR 880.5725	21 CFR 886.4350
DEVICE CLASSIFICATIONS	Class II	Class I
PRODUCT CODES	MRH (Pump, infusion, ophthalmic)	HMZ (Trabeculotome)

PREDICATE DEVICES:

DEVICE NAME	**510(K) NUMBER**
iTrack Catheter (Ellex) ** primary predicate device*	K080067
VISCO360 Viscosurgical System (Sight Sciences)	K171905

REFERENCE DEVICES:

DEVICE NAME	**510(K) NUMBER**
Harms Trabeculotomy Probe (Katena)	Class I exempt
Kahook Dual Blade (New World Medical)	Class I exempt
Nylon or Prolene Suture	Multiple

DESCRIPTION OF THE DEVICE:

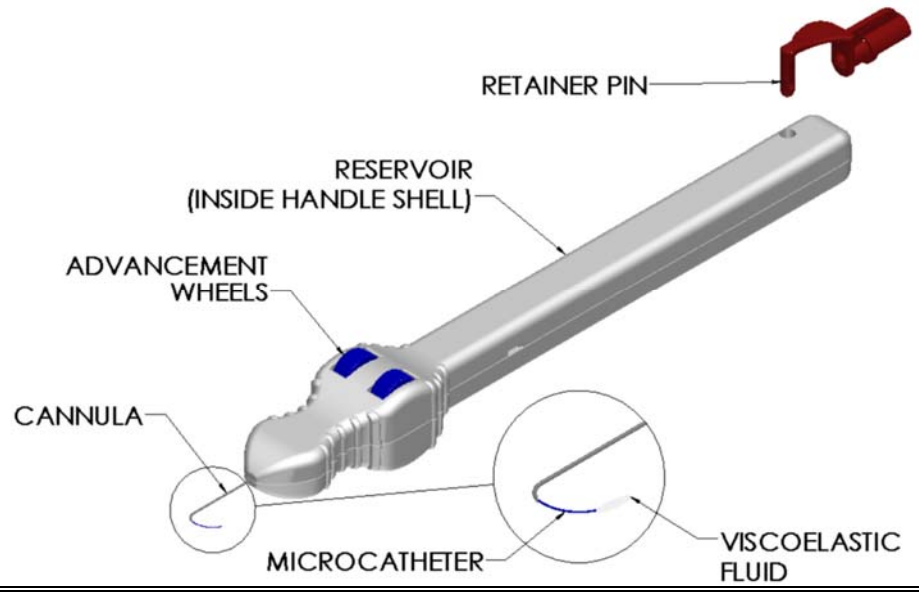
The Sight Sciences OMNI™ Surgical System ("OMNI") is a sterile, single use, manually operated instrument used by ophthalmologists to deliver small, controlled amounts of viscoelastic into the anterior segment of the eye during ophthalmic surgery. It is also indicated to cut trabecular meshwork tissue during trabeculotomy procedures.

The OMNI is designed to function with commonly used viscoelastic fluids made commercially available by companies such as Abbott Medical Optics (AMO), Bausch & Lomb, and Alcon. The OMNI dispenses fluid on the principle of exchanging volumes much like a syringe. The handheld instrument includes a cannula, microcatheter, internal reservoir and plunger tube, and finger wheels. The finger wheels on the handle of the device are used advance and retract the microcatheter. In addition, when the device is being used to deliver viscoelastic, retraction of the microcatheter causes the plunger tube to advance into the viscoelastic fluid reservoir thereby dispensing viscoelastic fluid.

The microcatheter can be advanced/retracted up to 20 mm per cycle. The microcatheter can be fully advanced/retracted up to 5 times (i.e. 5 full cycles of 20 mm each). Dispensation of viscoelastic can only occur during the first two 20-mm cycles.

The wheels are located on both sides 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.

OMNI Surgical System



INDICATIONS FOR USE:

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.

INTENDED USE (IN COMPARISON TO PREDICATE):

The OMNI Surgical System and the predicate devices (iTrack and VISCO360) are surgical tools for delivery of small amounts of viscoelastic fluid into the anterior segment. Like the reference devices (Harms Trabeculotome, Kahook Dual Blade, and prolene/nylon sutures), the OMNI device may also be used to cut trabecular meshwork when a trabeculotomy is indicated.

TECHNICAL CHARACTERISTICS (IN COMPARISON TO PREDICATE):

The technical features of the OMNI Surgical System are substantially equivalent to the Ellex iTrack™ Interventional Canaloplasty Microcatheter (K080067) and the Sight Sciences VISCO360® Viscosurgical System (K171905). Both are manually operated devices for the controlled delivery of small amounts of viscoelastic fluid. Fluid is dispensed from each system on the principle of exchanging volumes much like a syringe.

The intended use and technical features of the OMNI are also substantially equivalent to the following reference devices: Katena Harms Trabeculotomy Probe (Class I Exempt), the New World Medical Kahook Dual Blade (Class I Exempt), and Nylon or Prolene Sutures (Class II). All of these devices are manually operated for the cutting of trabecular meshwork when a trabeculotomy is indicated.

Table 1 compares the attributes of the OMNI with these predicate and reference devices.

Table 1: Technological Characteristics Comparison
Sight Sciences OMNI Surgical System and the Predicate and Reference Devices

Characteristic	OMNI Surgical System	Ellex's (iScience) iTrack (Primary Predicate)	Sight Sciences' VISCO360 Viscosurgical System (Predicate Device)	Katena's Harms Trabeculotomy Probe (Reference Device)	New World Medical's Kahook Dual Blade (Reference Device)	Nylon or Prolene Suture (Reference Device)
Intended Use	• Delivery of small amounts of viscoelastic fluid during ophthalmic surgery • Cutting of trabecular meshwork when a trabeculotomy is indicated	• Delivery of small amounts of viscoelastic fluid during ophthalmic surgery	• Delivery of small amounts of viscoelastic fluid during ophthalmic surgery	• Cutting of trabecular meshwork when a trabeculotomy is indicated	• Cutting of trabecular meshwork when a trabeculotomy is indicated	• Soft tissue approximation and various other uses including cutting of trabecular meshwork when a trabeculotomy is indicated
Indication for Use	The OMNI System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon or HealonGV 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.	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.	The VISCO360 Viscosurgical System is a manually operated device for delivery of small amounts of viscoelastic fluid, for example Healon or HealonGV from Abbott Medical Optics (AMO), Amvisc from Bausch & Lomb, or PROVISC from Alcon, during ophthalmic surgery.	Cutting of trabecular meshwork when a trabeculotomy is indicated	Cutting of trabecular meshwork when a trabeculotomy is indicated	Soft tissue approximation and various other uses including cutting of trabecular meshwork when a trabeculotomy is indicated

Characteristic	OMNI Surgical System	Ellex's (iScience) iTrack (Primary Predicate)	Sight Sciences' VISCO360 Viscosurgical System (Predicate Device)	Katena's Harms Trabeculotomy Probe (Reference Device)	New World Medical's Kahook Dual Blade (Reference Device)	Nylon or Prolene Suture (Reference Device)
Regulation	Primary: 880.5725 (Infusion Pump) Secondary: 886.4350 (Manual ophthalmic surgical instrument)	Primary: 876.1500 (Endoilluminator) Secondary: 886.4350 (Manual ophthalmic surgical instrument)	880.5725 (Infusion Pump)	886.4350 (Manual ophthalmic surgical instrument)	886.4350 (Manual ophthalmic surgical instrument)	878.5010 and 878.5020 (Nonabsorbable surgical suture)
Device Class	Class II	Class II	Class II	Class I, exempt	Class I, exempt	Class II
Product Code	Primary: MRH (Ophthalmic Infusion Pump, Class II) Secondary: HMZ (Trabeculotome, Manual ophthalmic surgical instrument, Class I exempt)	Primary: MPA (for endoilluminator, Class II) Secondary: HMX (Ophthalmic Cannula, Manual ophthalmic surgical instrument, Class I Exempt)	MRH (Ophthalmic Infusion Pump, Class II)	HMZ (Trabeculotome, Manual ophthalmic surgical instrument, Class I exempt)	HNN (Ophthalmic Knife, Manual ophthalmic surgical instrument, Class I exempt)	GAW and GAR (Nonabsorbable, Synthetic Suture, Class II)
Target Anatomy	Anterior Segment including Schlemm's Canal/Trabecular Meshwork	Schlemm's Canal/Trabecular Meshwork	Anterior Segment including Schlemm's Canal	Schlemm's Canal/Trabecular Meshwork	Schlemm's Canal/Trabecular Meshwork	Anywhere, including Schlemm's Canal/Trabecular Meshwork
Operating Principle	Manual	• Manual (microcatheter) • Powered (endoilluminator)	Manual	Manual	Manual	Manual

Characteristic	OMNI Surgical System	Ellex's (iScience) iTrack (Primary Predicate)	Sight Sciences' VISCO360 Viscosurgical System (Predicate Device)	Katena's Harms Trabeculotomy Probe (Reference Device)	New World Medical's Kahook Dual Blade (Reference Device)	Nylon or Prolene Suture (Reference Device)
Design/Mechanism of Action	• Flexible microcatheter for dispensation of viscoelastic • Microcatheter has a round, bolus, atraumatic tip • Proximal handle • Handle has internal viscoelastic reservoir and plunger tube • Finger wheel for advancing and retracting microcatheter. • Tactile and audible clicks indicate precise advancement. • Viscoelastic dispensed during retraction • Flexible microcatheter introduced into Schlemm's canal and pulled through to cut trabecular meshwork	• Flexible microcatheter for dispensation of viscoelastic • Microcatheter has a round, bolus, atraumatic tip • Microcatheter attaches at proximal end to Ellex ViscoInjector to dispense viscoelastic using a knob • Microcatheter manually advanced by clinician • Tactile and audible clicks indicate precise advancement. • Optical fiber provide illumination at tip of catheter	• Flexible microcatheter for dispensation of viscoelastic • Microcatheter has a round, bolus, atraumatic tip • Proximal handle • Handle has internal viscoelastic reservoir and plunger tube • Finger wheel for advancing and retracting microcatheter. • Tactile and audible clicks indicate precise advancement. • Viscoelastic dispensed during retraction	• Proximal handle • Distal blunt end manually pulled through trabecular meshwork with proximal handle	• Proximal handle • Distal sharp end manually pushed through trabecular meshwork with proximal handle	Nonabsorbable, sterile, flexible thread pulled through trabecular meshwork
Viscoelastic	Supplied separately. Viscoelastic loaded into device prior to use.	Supplied separately. Cartridge attaches to the device.	Supplied separately. Viscoelastic loaded into device prior to use.	N/A	N/A	N/A
Sterile and Single Use	Provided sterile. Single use	Provided sterile. Single use.	Provided sterile. Single use.	Provided non-sterile. Reusable.	Provided sterile. Single use.	Provided sterile. Single use.

Characteristic	OMNI Surgical System	Ellex's (iScience) iTrack (Primary Predicate)	Sight Sciences' VISCO360 Viscosurgical System (Predicate Device)	Katena's Harms Trabeculotomy Probe (Reference Device)	New World Medical's Kahook Dual Blade (Reference Device)	Nylon or Prolene Suture (Reference Device)
Passive or Energized Device to Dispense Viscoelastic	Passive	Passive	Passive	N/A	N/A	N/A
Dispensing Control	Manual rotation of the finger wheel at the distal end of the device	Rotational action via a knob on the ViscoInjector to dispense viscoelastic fluid	Manual rotation of the finger wheel at the distal end of the device	N/A	N/A	N/A
Dispensing Mechanism	Syringe (Volume exchange)	Syringe (Volume exchange)	Syringe (Volume exchange)	N/A	N/A	N/A
Materials	Cannula - Stainless steel Microcatheter – Polyamide (Nylon)	Microcatheter – polyamide	Cannula - Stainless steel Microcatheter - Nylon	Stainless Steel & Titanium	Stainless steel	Polypropylene or nylon
Interface	Handheld	Handheld	Handheld	Handheld	Handheld	Handheld
Microcatheter shaft/Probe OD	200 microns	200 microns	200 microns	300 microns	N/A	Varies (typically 4-0 or 200 microns or 5-0 or 150 microns for suture trabeculotomy)

PERFORMANCE DATA:

The OMNI's descriptive characteristics are well-defined and adequate to ensure equivalence to the predicate devices. Additionally, the following performance testing and inspection was conducted on the OMNI device: dimensional and visual inspections, visual inspection of labeling and component inspections, mechanical testing of joint strength and actuation force, simulated use testing, and human cadaver eye performance testing. Acceptance criteria was based on predicate VISCO360's dispensing performance, intrinsic strength of the materials, and the load and conditions to which the OMNI would be subjected during use.

Testing demonstrated that the OMNI performs as intended and is functionally equivalent to the predicate devices.

CONCLUSION:

The Sight Sciences OMNI Surgical System meets all product design requirements and applicable standards. The OMNI System shares the same intended use, key technological characteristics, and principle of operation as the predicate devices. Therefore, the device has been shown to be substantially equivalent to the predicate devices.