DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 27, 2017

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

Re: K171905
Trade/Device Name: VISCO 360 Viscosurgical System
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: MRH
Dated: June 23, 2017
Received: June 26, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -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

FDA Form 3881: Indications for Use

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171905

Device Name

VISCO360® VISCOSURGICAL SYSTEM

Indications for Use *(Describe)*

The Sight Sciences 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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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Tel: (877) 266-1144

OFFICIAL CORRESPONDENT

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Menlo Park, CA 94025

Anne@sightsciences.com
661-645-8546 (cell)

TRADE NAME: VISCO360® Viscosurgical System

CLASSIFICATION NAME: Pump, infusion, ophthalmic

DEVICE CLASSIFICATION AND PRODUCT CODE: Class II per 21 CFR 880.5725, MRH

PREDICATE DEVICE:

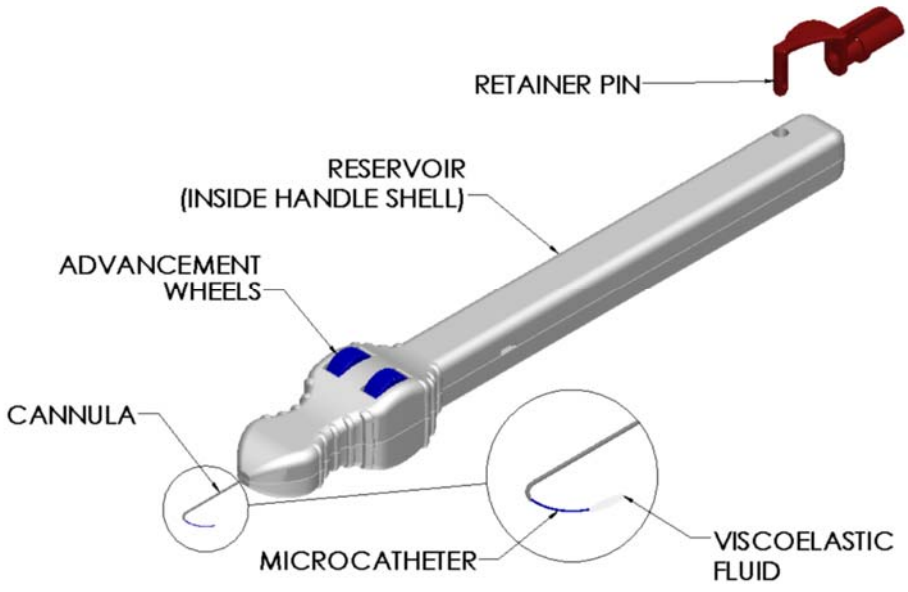
DEVICE NAME	510K NUMBER
Sight Sciences Viscoelastic Injector	K143205

SUBSTANTIAL EQUIVALENCE:

The modified Sight Sciences VISCO360® Viscosurgical System is substantially equivalent to the original Sight Sciences Viscoelastic Injector cleared under K143205. A minor design modification was made to the O-ring to reduce the force required to advance the plunger tube into the viscoelastic reservoir. The modified VISCO360 device has the same intended use and basic scientific technology as the original model.

DESCRIPTION OF THE DEVICE:

The Sight Sciences VISCO360 Viscosurgical System is a sterile, single use, manually operated instrument used by ophthalmologists to deliver small amounts of viscoelastic into the eye during ophthalmic surgery. The VISCO360 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 VISCO360 dispenses fluid on the principle of exchanging volumes much like a syringe. The handheld instrument includes a cannula, microcatheter, internal reservoir, plunger tube and finger wheels. The finger wheels on the handle of the device are used to advance the plunger tube into the viscoelastic fluid reservoir thereby dispensing viscoelastic fluid. The finger wheels are placed on both sides of the handle facilitating viscoelastic delivery in either the left or right eye (OD or OS) using either hand.



VISCO360 Viscosurgical System

INDICATIONS FOR USE:

The Sight Sciences 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.

TECHNICAL CHARACTERISTICS:

The VISCO360 device consists of the following components and accessories:

- Cannula
- Microcatheter
- Internal reservoir
- Plunger tube
- Finger wheels

The VISCO360 dispenses fluid on the principle of exchanging volumes much like a syringe. The components responsible for the fluid dispensing are the following:

- The reservoir within the handle is analogous to a syringe plunger. Prior to use, the viscoelastic fluid is loaded into the reservoir.
- The plunger tube is connected to the microcatheter and it communicates with the reservoir. During use the plunger tube acts like a graduated cylinder.
- The microcatheter, initially located within the cannula, advances and retracts from the device to dispense fluid. The microcatheter is analogous to a syringe dispensing-tip.
- The user interfaces with the device by using the finger wheels. This action is analogous to moving the dispensing tip to the desired location and depressing the plunger handle.

PERFORMANCE DATA:

The VISCO360's descriptive characteristics are well-defined and adequate to ensure equivalence to the predicate device. Additionally, performance testing was conducted to evaluate friction force necessary to advance the plunger tube into the reservoir. Acceptance criteria was based on the modified device having a significant reduction in this friction force in comparison to the primary predicate device.

Testing demonstrated that the modified device passed this functional test.

CONCLUSION:

The Sight Sciences VISCO360 Viscosurgical System meets all product design requirements and applicable standards and embodies technological characteristics similar to the predicate device, the device has been shown to be substantially equivalent to the predicate device, and is safe and effective.