4.0 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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

APPLICANT:	Sight Sciences, Inc. 3169 Sacramento Street San Francisco, CA 94115 Tel: (415) 889-0550
CONTACT PERSON:	Judy Gordon, D.V.M. ClinReg Consulting Services, Inc. 733 Bolsana Drive Laguna Beach, CA 92651 judy@clinregconsulting.com Tel: (949) 715-0609 Fax: (949) 715-0610
TRADE NAME:	Viscoelastic Injector
COMMON NAME:	Viscoelastic Injector
CLASSIFICATION NAME:	Pump, Infusion, Ophthalmic
DEVICE CLASSIFICATION:	Class II; 21 CFR 880.5725
PRODUCT CODE:	MRH
PREDICATE DEVICE:	iScience Surgical Corporation ViscoInjector K050716

OCT 2 2 2013

4.1 DEVICE DESCRIPTION

The Sight Sciences Viscoelastic Injector is a sterile, single use, manually operated instrument used by ophthalmologists to deliver small amounts of viscoelastic into the eye during ophthalmic surgery. The Viscoelastic Injector 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 Sight Sciences Viscoelastic Injector dispenses fluid on the principle of exchanging volumes much like a syringe. The handheld instrument includes a cannula, injection tube, 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.

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

- Prior to use, the viscoelastic fluid is loaded into the reservoir (polycarbonate) contained within the handle.
- The reservoir communicates with the plunger tube (stainless steel) which is connected to the injection tube (polyimide). During use, the plunger tube displaces volume in the reservoir thereby dispensing fluid.
- The injection tube is initially located within the cannula (stainless steel), advances and retracts from the device to dispense fluid. The injection tube is analogous to a syringe dispensing-tip.
- The finger wheels move the injection tube in and out of the cannula tip and drive the plunger tube into the reservoir to dispense viscoelastic fluid in a controlled manner.

4.2 INDICATION FOR USE

The Sight Sciences Viscoelastic Injector 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.

4.3 TECHNOLOGICAL CHARACTERISTICS COMPARISON

The intended use and technical features of the Sight Sciences Viscoelastic Injector are substantially equivalent to the ViscoInjector (K050716) marketed by iScience Surgical. Both devices are manually operated for controlled delivery of small amounts of viscoelastic fluid. Fluid is dispensed from each system on the principle of exchanging volumes much like a syringe. Table 1 compares the attributes of the iScience ViscoInjector with the Sight Sciences Viscoelastic Injector.

TABLE 1
TECHNOLOGICAL CHARACTERISTICS COMPARISON
SIGHT SCIENCES VISCOELASTIC INJECTOR AND THE PREDICATE DEVICE

ATTRIBUTE	SIGHT SCIENCES VISCOELASTIC INJECTOR	ISCIENCE VISCOINJECTOR PREDICATE DEVICE
Sterile & Single-Use	Yes	Yes
Operation Control	User	User
Ergonomics	Distally-positioned delivery wheel	Proximally-positioned delivery wheel
Passive or Energized Device	Passive	Passive
Reservoir	Internal and Integral Reservoir	Commercial Viscoelastic Cartridge
Dispensing Mechanism	Syringe (Volume Exchange)	Syringe (Volume Exchange)
User Determines Amount of fluid to Dispense	Yes, by rotating the distal finger wheel	Yes, by rotating the proximal knob

4.4 BRIEF SUMMARY OF PERFORMANCE TEST RESULTS

The device's descriptive characteristics are well-defined and adequate to ensure equivalence of the Sight Sciences Viscoelastic Injector. Additionally, performance testing was designed and conducted to evaluate device integrity, delivery of viscoelastic solutions, simulated use testing, and dimensional and visual inspections. Acceptance criteria was based on viscoinjector dispensing performances, intrinsic strength of the materials, and the load to which the Sight Science Viscoelastic Injector would be subjected during intended use.

Testing demonstrated that the proposed device performs as intended and is functionally equivalent to the predicate device.

4.5 CONCLUSION

The Viscoelastic Injector by Sight Sciences, Inc. meets all product design requirements and applicable standards and embodies technological characteristics similar to the predicate devices, the device has been shown to be substantially equivalent to the predicate devices, and is safe and effective.

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

October 22, 2013

Sight Sciences, Inc.
% Judy F. Gordon, D.V.M
ClinReg Consulting Services, Inc.
733 Bolsana Drive
Laguna Beach, CA 92651

Re: K132494
Trade/Device Name: Sight Sciences Viscoelastic Injector
Regulation Number: 21 CFR 880.5725
Regulation Name: Pump, Infusion, Ophthalmic
Regulatory Class: Class II
Product Code: MRH
Dated: August 19, 2013
Received: August 20, 2013

Dear Dr. Gordon:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Kesia Y. Alexander -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

Indications for Use

510(k) Number: K132494

Device Name: Viscoelastic Injector

Indications For Use:

The Sight Sciences Viscoelastic Injector 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.

Prescription Use___X_____ AND/OR Over-The-Counter Use_____
(part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Daniel P. Fedorko
2013.10.16 14:12:59 -04'00'

(Division Sign-Off)
Division of Ophthalmic and Ear, Nose, and Throat Devices
510(k) Number:_____K132494_____