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

August 11, 2016

Optics Laboratory, Inc.
% Mr. Paul Kramsky
President
Rockin' Regulatory, Inc.
21831 Tumbleweed Circle
Lake Forest, CA 92630

Re: K161622
Trade/Device Name: LensGiene™ Sterile Saline Solution
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC, LPN
Dated: June 10, 2016
Received: June 13, 2016

Dear Mr. Kramsky:

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,

Kesia Alexander

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161622

Device Name
LensGiene(TM) Sterile Saline Solution

Indications for Use *(Describe)*
The LensGiene™ Sterile Saline Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The LensGiene™ Sterile Saline Solution is for rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse contact lenses.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary for the LensGiene™ Sterile Saline Solution

Submission Sponsor:
Optics Laboratory, Inc.
9480 Telstar Ave Ste 3
El Monte, CA 91731-2988
Telephone: 626-350-1926
Fax: 626-350-1906
FDA Establishment Registration #: 3001918419

Submission Correspondent:
Rockin' Regulatory, Inc.
21831 Tumbleweed Circle
Lake Forest, CA 92630
Telephone: 949-636-1464
Contact: Paul Kramsky, President
Email: pkramsky@cox.net

Date Prepared:
June 10, 2016

Device Name:

Trade/Proprietary Name:	LensGiene™ Sterile Saline Solution
Classification Name:	Contact Lens Care Products
Product Code:	MRC and LPN
Regulation Number:	21 CFR 886.5918 (Rigid Gas Permeable Contact Lens Care Products) 21 CFR 886.5928 (Soft (hydrophilic) Contact Lens Care Products)
Device Classification:	II
Review Panel:	Ophthalmic

Predicate Devices:
The LensGiene™ Sterile Saline Solution is substantially equivalent to the Menicon Co., Ltd. Saline Rinse Solution (K151768) and the Optics Laboratory, Inc. EyeCept™ Sterile Saline Solution (K110221).

Device Description:
The LensGiene™ Sterile Saline Solution is a sterile, preservative-free, aqueous solution of sodium chloride, boric acid, and sodium borate provided in single does, carry-on size 10 ml bottles. The sterile saline solution has a pH 7.2-7.8 and a tonicity of 290-320 mOsm/kg. It rinses loose debris and cleaning solution off soft (hydrophilic), rigid gas permeable (RGP) and hard contact lenses prior to insertion. The rinsing solution removes

debris and bacteria following proper disinfection as recommended by the eye care practitioner. The sterile saline solution can be used to rinse contact lens cases, rinse lenses as needed throughout the day and to fill the concave posterior surface of scleral lenses prior to insertion to provide a more natural environment than currently approved multipurpose solutions which contain preservatives and osmolarity agents that are not designed to be held against the cornea for extended periods of time.

The LensGiene™ Sterile Saline Solution is a clear solution and should not be used if cloudy or discolored. The individual 10 ml bottle should be discarded after opening and use and should not be used after its labeled expiry date.

Indications for Use:
The LensGiene™ Sterile Saline Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The LensGiene™ Sterile Saline Solution is for rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse contact lenses.

Performance Data:
Non-Clinical Data
Non-clinical tests were unnecessary for this application because this testing was previously submitted for this solution under cleared 510(k) K110221.

Clinical Data
Clinical studies were unnecessary for this application because this solution was previously cleared for rinsing soft (hydrophilic) contact lenses under K110221.

Conclusion
Based upon the composition of the saline solution and previous test data submitted in K110221, the LensGiene™ Sterile Saline Solution is as safe, as effective and performs as well as the predicate devices. A comparison of the LensGiene™ Sterile Saline Solution and the predicate devices is presented in Table 1.

Substantial Equivalence:

The claim of substantial equivalence to the previously cleared Menicon Co., Ltd. Saline Rinse Solution (K151768) and the Optics Laboratory, Inc. EyeCept™ Sterile Saline Solution (K110221) is supported by the following Comparison of Characteristics in Table 1. The LensGiene™ Sterile Saline Solution and the predicates are similar in composition and intended use. Therefore, the LensGiene™ Sterile Saline Solution is substantially equivalent to the predicate devices.

Table 1 Comparison of Characteristics

	LensGiene™ Sterile Saline Solution	Menicon Saline Rinse Solution	EyeCept™ Sterile Saline Solution
Device Name	Contact Lens Care Product	**SAME**	**SAME**
Trade Name	LensGiene™ Sterile Saline Solution	Menicon Saline Rinse Solution	EyeCept™ Sterile Saline Solution
Document Number	K161622	K151768	K110221
Classification	Ophthalmic	**SAME**	**SAME**
Product Code	MRC and LPN	**SAME**	LPN
Regulation Number	21 CFR 886.5918 21 CFR 886.5928	**SAME**	21 CFR 886.5928
Class	II	II	II
Intended Use	For use following proper lens disinfection as recommended by the eye care practitioner. The LensGiene™ Sterile Saline Solution is for rinsing soft (hydrophilic), rigid gas permeable and hard contact lenses prior to lens insertion. This solution may also be used as an insertion solution for large diameter (scleral) contact lenses, as a rinse for contact lens cases, and may be used as needed throughout the day to rinse contact lenses.	**SAME**	For rinsing soft contact lenses after cleaning and for wetting soft contact lenses after disinfection before use.
Volume	10 ml	5 ml	10 ml
Preservative Free	Yes	**SAME**	**SAME**
Container Usage	Single use	**SAME**	**SAME**
Sterility	Sterile	**SAME**	**SAME**
Materials	Plastic resin container with twist off cap	**SAME**	**SAME**
Biocompatibility	Evaluated in accordance with FDA Guidance for Contact Lens Care Products	**SAME**	**SAME**