July 31, 2020

Dry Eye Innovations, LLC
% Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Ln
West Linn, OR 97068

Re: K201069
Trade/Device Name: VibrantVue Scleral Saline
Regulation Number: 21 CFR 886.5918
Regulation Name: Rigid Gas Permeable Contact Lens Care Products
Regulatory Class: Class II
Product Code: MRC
Dated: June 29, 2020
Received: July 2, 2020

Dear Bret Andre:

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,

J. Angelo Green, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201069

Device Name
VibrantVue Scleral Saline

Indications for Use *(Describe)*
The VibrantVue Scleral Saline is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The VibrantVue Scleral Saline is for rinsing large diameter (scleral) rigid gas permeable (RGP) 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.

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510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

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

The assigned 510(k) number is: K201069

I. SUBMITTER

Date Prepared: June 29th, 2020

Name: **Dry Eye Innovations LLC**
Address: 1200 Harger Rd
Suite 211
Oak Brook, IL 60523

Contact Person: Donald R. Sanders
Manager and CEO
Phone number: (630) 530-9700

Consultant: Bret Andre
EyeReg Consulting, Inc.
6119 Canter Ln.
West Linn, OR 97068
Phone number: (503) 372-5226

II. DEVICE

Trade Name: **VibrantVue Scleral Saline**

Common Name: Contact Lens Insertion Solution

Classification Name: Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)

Regulatory Class: Class II

Product Code: MRC

III. PREDICATE DEVICE

The VibrantVue Scleral Saline is substantially equivalent in terms of actions and indications to the following predicate device:

- "Menicon Saline Rinse Solution"
  By Menicon Co., Ltd.
  510(k) number: K151768
  Device Classification: II

IV. DEVICE DESCRIPTION

The VibrantVue Scleral Saline is a sterile, preservative-free, unbuffered saline solution in a single dose 5 ml vial. The VibrantVue Scleral Saline is a 0.9 % saline solution that conforms to the requirements of USP saline. The rinsing solution removes loose debris and lens cleaners off rigid gas permeable (RGP) contact lenses following proper disinfection as recommended by the eye care practitioner. The sterile solution can be used to rinse contact lens cases and contact lenses as needed throughout the day.

V. INDICATIONS FOR USE

The VibrantVue Scleral Saline is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The VibrantVue Scleral Saline is for rinsing large diameter (scleral) rigid gas permeable (RGP) 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The VibrantVue Scleral Saline solution is substantially equivalent to the predicate device in terms of the following:

- Intended use
- Indications for use
- Actions
- Classification – Rigid Gas Permeable Contact Lens Care Products (21 CFR 886.5918)
- How supplied (sterile, single dose)
- Unbuffered, preservative free formulation
- Formulation conforms to USP monograph for 0.9% saline

The following matrix illustrates the intended use and other characteristics of the VibrantVue Scleral Saline solution, as well as the predicate device.

	Visionary Optics LLC **VibrantVue Scleral Saline**	**Menicon Co., Ltd.** **Menicon Saline Rinse Solution**
	New Device	Predicate Device (K151768)
Intended Use	The VibrantVue Scleral Saline solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The VibrantVue Scleral Saline solution is for rinsing large diameter (scleral) rigid gas permeable (RGP) 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.	The Menicon Saline Rinse Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner. The Menicon Saline Rinse 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.
Classification	21 CFR 886.5918	21 CFR 886.5918 ; 21 CFR 886.5928
Product Code	MRC	MRC; LPN
Class	Class II	Class II
Volume	5 mL per dose	5 mL per dose
Preservative Free	Yes	Yes
Single or Multi Dose	Single Dose	Single Dose
Sterility	Sterile	Sterile
Container	Plastic resin container with twist off cap	Plastic resin container with twist off cap
Unbuffered	Yes	Yes
Formulation Conforms to USP Monograph for 0.9% Saline	Yes	Yes

VII. PERFORMANCE DATA

~ Non-Clinical Studies ~

A series of studies were completed to demonstrate the substantial equivalence of the VibrantVue Scleral Saline solution to the predicate device. Results of non-clinical testing demonstrate:

- The VibrantVue Scleral Saline solution is physically compatible with currently marketed rigid gas permeable contact lenses
- The packaging is non-toxic and non-irritating
- The VibrantVue Scleral Saline solution is stable and sterile throughout the proposed expiration date

~ Clinical Studies ~

Clinical studies involving the saline solution were unnecessary for this application. The VibrantVue Scleral Saline is a 0.9 % saline solution that meets the requirements of USP saline. Lens care solutions used with this saline solution are already cleared for use as cleaning, rinsing, disinfection and storage solutions for contact lenses.

VIII. CONCLUSIONS

Substantial Equivalence

Based on the composition of the solution and results of non-clinical testing presented in this Premarket Notification, the VibrantVue Scleral Saline solution is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.