October 12, 2022

Chemtex USA Inc.
% Bret Andre
Principal Consultant
EyeReg Consulting, Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K221263
Trade/Device Name: Aqua Naina Plus Sterile Saline Solution, Aqua Naina Sterile Saline Solution
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: September 20, 2022
Received: September 20, 2022

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221263

Device Name
Aqua Naina Plus Sterile Saline Solution, Aqua Naina Sterile Saline Solution

Indications for Use *(Describe)*

Aqua Naina Plus Sterile Saline Solution

The Aqua Naina Plus Sterile Saline Solution for single use is indicated for rinsing soft (hydrophilic) and rigid gas permeable (hard) contact lenses prior to lens insertion. This solution may 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 Aqua Naina Plus Sterile Saline Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner.

Aqua Naina Sterile Saline Solution

The Aqua Naina Sterile Saline Solution is indicated for rinsing soft (hydrophilic) and rigid gas permeable (hard) contact lenses prior to lens insertion and following proper lens disinfection as recommended by the eye care practitioner. The Aqua Naina Sterile Saline Solution may be used as needed throughout the day to rinse contact lenses and contact lens cases.

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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Special 510 (k) Summary

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: K221263

I. SUBMITTER

Date Prepared: September 20th, 2022

Name: Chemtex USA Inc
Address: 27-29 Dwight Place
Fairfield, NJ 07004-3303

Contact Person: Haribabu Talasila
President
Phone number: (732) 447-4353

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

II. DEVICE

Trade Name: **Aqua Naina Sterile Saline Solution; Aqua Naina Plus Sterile Saline Solution**

Common Name: Contact Lens Saline Solution

Classification Name: Accessories, Soft Lens Products (21 CFR 886.5928)
Products, Contact Lens Care, Rigid Gas Permeable (21 CFR 886.5918)

Regulatory Class: Class II

Product Code: LPN; MRC

III. PREDICATE DEVICE

Aqua Naina and Aqua Naina Plus Sterile Saline Solutions are substantially equivalent to the following predicate devices:

- "Aqua Naina Sterile Saline Solution" (Primary Predicate)
  By Chemtex Usa, Inc.
  510(k) number; **K193441**
- "PuriLens Plus Preservative Free Saline"
  By The LifeStyle Company, Inc.
  510(k) number; **K200747**
- "Menicon Saline Rinse Solution"
  By Menicon Co., Ltd.
  510(k) number; **K151768**
- "VibrantVue Scleral Saline"
  By Dry Eye Innovations, LLC
  510(k) number; **K201069**

IV. DEVICE DESCRIPTION

Aqua Naina Plus Sterile Saline Solution

Aqua Naina Plus Sterile Saline Solution is a sterile, preservative-free, buffered, isotonic, clear (colorless) aqueous solution containing isotonic solution of sodium chloride, boric acid and sodium borate in purified water USP. Aqua Naina Plus Sterile Saline Solution has pH of 7.00 to 7.40 and Osmolality of 290 to 320 mOsmol/kg. The Sterile Saline Solution is packed in single dose 1 fl oz (30 ml) high density polyethylene (HDPE) container with a tamper evident seal. Aqua Naina Plus Sterile Saline Solution is for single use only.

Aqua Naina Sterile Saline Solution

Aqua Naina Sterile Saline Solution is a sterile, preservative-free, buffered, isotonic, clear (colorless) aqueous solution containing isotonic solution of sodium chloride, boric acid and sodium borate in purified water USP. Aqua Naina Sterile Saline Solution has pH of 7.00 to 7.40 and Osmolality of 290 to 320 mOsmol/kg. The Sterile Saline Solution is packed in a multidose 4 fl oz (118ml) high density polyethylene (HDPE) container with a tamper evident seal.

V. INDICATIONS FOR USE

Aqua Naina Plus Sterile Saline Solution

The Aqua Naina Plus Sterile Saline Solution for single use is indicated for rinsing soft (hydrophilic) and rigid gas permeable (hard) contact lenses prior to lens insertion. This solution may 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 Aqua Naina Plus Sterile Saline Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner.

Aqua Naina Sterile Saline Solution

The Aqua Naina Sterile Saline Solution is indicated for rinsing soft (hydrophilic) and rigid gas permeable (hard) contact lenses prior to lens insertion and following proper lens disinfection as recommended by the eye care practitioner. The Aqua Naina Sterile Saline Solution may be used as needed throughout the day to rinse contact lenses and contact lens cases.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The Aqua Naina Plus Sterile Saline Solution is substantially equivalent to the predicate devices (cleared under K200747, K193441 and K151768) in terms of the following:

- Intended use (K200747)
- Indications for use (K200747)
- Actions (K200747)
- Product Code (K200747) - LPN; MRC
- Classification (K200747) – Accessories, Soft Lens Products (21 CFR 886.5928); Products, Contact Lens Care, Rigid Gas Permeable (21 CFR 886.5918)
- Production method – Terminal sterilization by gamma irradiation (K193441)
- Single use (K151768)

The Aqua Naina Sterile Saline Solution is substantially equivalent to the predicate devices (cleared under K200747, K193441 and K151768) in terms of the following:

- Intended use (K193441, K151768)
- Indications for use (K193441, K151768)
- Actions (K193441, K151768)
- Product Code (K193441, K151768) - LPN; MRC
- Classification (K193441, K151768) – Accessories, Soft Lens Products (21 CFR 886.5928); Products, Contact Lens Care, Rigid Gas Permeable (21 CFR 886.5918)
- Production method – Terminal sterilization by gamma irradiation (K193441)
- Packaging/multi-use (K193441 & K200747)

The following tables compare the regulatory and technological features of the Aqua Naina Plus Sterile Saline Solution compared to the predicate devices:

	Aqua Naina Plus Sterile Saline Solution	Aqua Naina Sterile Saline Solution	PuriLens Plus Preservative Free Saline	Menicon Saline Rinse Solution	Vibrant Vue Scleral Saline
Applicant	Chemtex Usa, Inc.	Chemtex Usa, Inc.	The LifeStyle Company, Inc.	Menicon Co., Ltd.	Dry Eye Innovations, LLC
Document Number	Subject Device	K193441	K200747	K151768	K201069
Product Code	LPN; MRC	LPN	LPN; MRC	LPN; MRC	MRC
Regulation Number	21 CFR 886.5928; 21 CFR 886.5918	21 CFR 886.5928	21 CFR 886.5928; 21 CFR 886.5918	21 CFR 886.5928; 21 CFR 886.5918	21 CFR 886.5918
Preservative Free	Yes	Yes	Yes	Yes	Yes
Supplied Sterile	Yes	Yes	Yes	Yes	Yes
Container Usage	Multi dose; Single dose	Multi dose	Multi dose	Single dose	Single dose
Packaging	high density polyethylene (HDPE) container with a tamper evident seal	high density polyethylene (HDPE) container with a tamper evident seal	Plastic resin container with puncture, reusable cap	Plastic resin container with twist off cap	Plastic resin container with twist off cap
Production Method	terminal sterilization by gamma irradiation	terminal sterilization by gamma irradiation	Not specified	aseptic blow-fill-seal process	aseptic blow-fill-seal process
Volume	Multi dose: 4oz (118 ml) Single dose: 1oz (30 ml)	4oz (118 ml)	4.05 oz (120 mL); 2.03 oz (60 mL)	5 ml	5 ml

	Indications for Use
Aqua Naina Plus Sterile Saline Solution (Subject Device)	<u>Aqua Naina Plus Sterile Saline Solution</u> The Aqua Naina Plus Sterile Saline Solution is for single use for rinsing soft (hydrophilic) and rigid gas permeable (hard) contact lenses prior to lens insertion. This solution may 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 Aqua Naina Plus Sterile Saline Solution is indicated for use following proper lens disinfection as recommended by the eye care practitioner. <u>Aqua Naina Sterile Saline Solution</u> The Aqua Naina Sterile Saline Solution is indicated for rinsing soft (hydrophilic) and rigid gas permeable (hard) contact lenses prior to lens insertion and following proper lens disinfection as recommended by the eye care practitioner. The Aqua Naina Plus Sterile Saline Solution may be used as needed throughout the day to rinse contact lenses and contact lens cases.

Aqua Naina Sterile Saline Solution (K193441)	Aqua Naina Sterile Saline Solution is indicated only for rinsing soft contact lenses after cleaning and disinfection before use.
PuriLens Plus Preservative Free Saline (K200747)	PuriLens Plus Preservative-Free Saline is indicated for use following proper lens disinfection as recommended by the eye care practitioner. PuriLens Plus Preservative-Free Saline 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.
Menicon Saline Rinse Solution (K151768)	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.
Vibrant Vue Scleral Saline (K201069)	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.

VII. PERFORMANCE DATA

The package volume change was validated using the same methods identified in K193441. No other performance data (clinical or non-clinical) are required for this special 510(k) submission.

VIII. CONCLUSIONS

Substantial Equivalence

Information presented in this premarket notification establishes that Aqua Naina and Aqua Naina Plus Sterile Saline Solutions is as safe and effective as the predicate devices when used in accordance with the labeled directions for use and indications.

Risks and Benefits

The risks and benefits of the subject device are the same as those normally attributed to contact lens saline rinsing and filling solutions.