May 26, 2020

Chemtex USA, Inc.
℅ Thomas Padula
VP Regulatory Compliance
Schiff & Company, Inc.
583 Mountain Avenue
North Caldwell, NJ 07006

Re: K193441
Trade/Device Name: 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
Dated: April 22, 2020
Received: April 22, 2020

Dear Thomas Padula:

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

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)*
K193441

Device Name
Aqua Naina Sterile Saline Solution

Indications for Use *(Describe)*
Aqua Naina Sterile Saline Solution is indicated only for rinsing soft contact lenses after cleaning and disinfection before use.

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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# 510(K) PREMARKET NOTIFICATION FOR AQUA NAINA STERILE SALINE SOLUTION CHEMTEX USA INC.

**510(k) Summary** (as required by 807.92)

(1) SUBMITTER:

CHEMTEX USA, INC.
27-29 DWIGHT PLACE
FAIRFIELD, NJ 07004-3303

Contact person: HARIBABU TALASILA, PRESIDENT
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Email: htalasila@chemtexusa.com

Contact Person: Mr. Hemant Shastri
Telephone No: 905 -212-9949
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Email: hshastri@chemtexinternational.com

Date prepared: December 9, 2019

(2) DEVICE NAME:

Trade Name: Aqua Naina Sterile Saline Solution
Common Name: Contact Lens Saline Solution
Classification Name: Soft contact lens care products
Device Classification: Class II
Regulation Number: 21 CFR 886.5928
Product Code: LPN

(3) PREDICATE DEVICE: Substantial equivalence is based on following legally marketed devices.

Eye-Cept Sterile Saline Solution K110221 **(Primary Predicate)**
Purilens Saline Solution – K002319
Unisol Saline Solution - P790011

(4) DESCRIPTION OF THE DEVICE:

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 6.30 to 7.80 and Osmolality of 280 to 320 mOsmol/kg The Sterile Saline Solution is packed in 4 fl oz (118ml) high density polyethylene (HDPE) container with a tamper evident seal.

(5) INDICATION FOR USE:

Aqua Naina Sterile Saline Solution is indicated only for rinsing soft contact lenses after cleaning and disinfection before use.

(6) COMPARISON WITH PREDICATE DEVICES: Following table is a comparison of Aqua Naina Sterile Saline Solution and predicate devices.

Aqua Naina Sterile Saline Solution is substantially equivalent in terms of it actions and indications for use, to Purilens Saline solution -K002319, Unisol Saline Solution P790011, Eye-Cept Saline Solution K110221 **(Primary Predicate)**, cleared for marketing under 510(K). Aqua Naina Sterile Saline Solution meets the guideline set forth in FDA's May 1,1997 Guidance for Industry, Premarket Notification 510(K) Guidance Document for Contact Lens Care Products.

| Equivalency | **Aqua Naina Sterile Saline Solution** | **Purilens Saline Solution K002319** | **Unisol P790011** | **Eye-Cept Saline Solution K110221 (Primary Predicate)** |
|---|---|---|---|---|
| Manufacturer | Niagara Pharmaceuticals, Inc. | Purilens Inc | Alcon | Optics Laboratory |
| Product Code | LPN | LPN | LPN | LPN |
| Regulation Number | 21 CFR 886.5928 | 21 CFR 886.5928 | 21 CFR 886.5928 | 21 CFR 886.5928 |
| Intended use (Indications for use) | Only for rinsing soft contact lenses after cleaning and for wetting soft contact lenses after disinfection before use. | For cleaning disinfection and storing of contact lenses | For heat disinfecting rinsing, storage and wetting of soft (hydrophilic) contact lenses | For rinsing soft (hydrophilic) contact lens after cleaning and wetting |
| Preservative free | Yes | Yes | Yes | Yes |
| Sterile | Yes | Yes | Yes | Yes |
| Aqueous Solution of NaCl and Borates | Yes | Yes | Yes | Yes |
| pH balanced | Yes | Yes | Yes | Yes |
| Volume | 4oz (118 ml) | 4oz (118 ml) | 4oz (118 ml) | 0.34oz (10ml) |

(7) PERFORMANCE STSTANDARDS APPLIED:

A Series of Studies were completed to demonstrate the substantial equivalence of Aqua Naina Sterile Saline Solution to the predicate devices. All testing was conducted in accordance with and in conformance to applicable device regulations and guidance. Results of all testing demonstrate the solution is non-toxic, is comparable to other currently marketed soft contact lens solution and is substantially equivalent to legally marketed predicates. These studies followed the "Testing Matrix for

Saline Solution" of the Guidance for Industry-Premarket Notification (510K) Guidance Document for Contact Lens Care Products, issued May 1, 1997" and included:

1. Sterility USP<71>
2. Bacteriostasis USP<71>
3. Ocular irritation
4. Cytotoxicity -Direct contact test
5. Cytotoxicity- MEM Elution test

| Standard | Title of Standard | Applied Section |
|---|---|---|
| ISO 10993-1:2009 | Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process | Section 15. Biocompatibility |
| ISO 10993-5:2009 | Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity | |
| ISO 10993-10:2010 | Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization | |

(8) CONCLUSION: Aqua Naina Sterile Saline Solution has the same intended use and technology characteristics as the predicate devices. Aqua Naina Sterile Saline Solution is as safe, as effective, and performs as well as the predicate devices.