January 13, 2022

Suzhou 3N Biological Technology Co., Ltd
Wang Xiaofang
Quality and Regulatory Division Manager
NO.218 Xinghu Street
Suzhou, Jiangsu 215000
China

Re: K211361
Trade/Device Name: 3N Contact Lenses Adjunct Cleaner
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LYL
Dated: December 10, 2021
Received: December 10, 2021

Dear Wang Xiaofang:

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)*
K211361

Device Name
3N Contact Lenses Adjunct Cleaner

Indications for Use *(Describe)*
3N Contact Lenses Adjunct Cleaner is intended for use as an adjunct in deproteinization and storage for soft hydrophilic contact lenses with only either OPTI-FREE EXPRESS Multi-Purpose Disinfecting Solution or Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution.

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.

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510(K) Summary

This 510(k) Summary is provided per the requirements of section 21 CFR 807.92.

The assigned 510(k) number is K211361.

Date Summary Prepared: 1/11/2022.

1. Submitter

Submitter's Name:	Suzhou 3N Biological Technology Co., Ltd
Contact person:	Wang Xiaofang Head of Quality and Regulatory
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2. Device

Trade Name	3N Contact Lenses Adjunct Cleaner
Common Name	Contact Lenses Adjunct Cleaner
Regulation Description	Contact lens care products
Regulation number	21 CFR 886.5928
Device Class	Class II
Product Code	LYL

3. Predicate Device

RIM-WIDE COMPANIES, INC. LENSERVER AUTOMATIC CONTACT LENS CLEANING ACCESSORY, K982115 (RIM-WIDE COMPANIES, INC.) FDA cleared on 01/13/1999.

4. Description of Proposed Device:

The proposed device, 3N Contact Lenses Adjunct Cleaner, Model TN083 is an electrical cleaner which is intended for use as an adjunct in deproteinization and storage for soft hydrophilic contact lenses using approved contact lens solutions.

The 3N Contact Lenses Adjunct Cleaner adopt the principle of protein electrophoresis, take advantage of the characteristics that negatively charged protein in certain environment and swarm towards positive pole in electric field, then the tear protein will be removed from the surface and air holes of contact lens and absorbed by anodic cleaning probe to achieve the goal of cleaning contact lenses.

The cleaning components of the 3N Contact Lenses Adjunct Cleaner (Model: TN083) consist of a cleaning unit (Power Base) and a partitioned fluid reservoir functioning as the cleaning chamber.

The cleaning chamber is detachably connected to the cleaning unit (power base). In the cleaning chamber, there are two independent cleaning tanks; and there is a cleaning probe on each side of the cleaning tank, namely electrode. In the cleaning unit, the circuit board is fixedly provided with electrode connectors electrically connected to the circuit board. The end of the electrode connector can be stretched and elastically connected with the bottom of the electrode.

5. Indications for Use

3N Contact Lenses Adjunct Cleaner is intended for use as an adjunct in deproteinization and storage for soft hydrophilic contact lenses with only either OPTI-FREE EXPRESS Multi-Purpose Disinfecting Solution or Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution.

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6. Comparison of Technological Characteristics with the Predicate Devices

The following table compares the device to the predicate device with basic technological characteristics.
Both subject and predicate devices are electrical contact lens cleaning device and used in conjunction with approved contact lens solutions.
3N Contact Lenses Adjunct Cleaner, TN083 has been compared to LENSERVER Automatic Contact Lens Cleaning Accessory as a predicate device for substantial equivalence. A table comparing the two devices is provided as follows:

Features	Proposed Device (K211361)	Predicate Device (K982115)	Comparison
Product code	LYL	LYL	Same
Regulation No.	21 CFR 886.5928	21 CFR 886.5928	Same
Device Class	Class II	Class II	Same
Indications for Use	3N Contact Lenses Adjunct Cleaner is intended for use as an	The LENSERVER Automatic Contact Lens Cleaning Accessory	Similar Note 1

	adjunct in deproteinization and storage for soft hydrophilic contact lenses with only either OPTI-FREE EXPRESS Multi-Purpose Disinfecting Solution or Bausch & Lomb ReNu MultiPlus Multi-Purpose Solution.	is intended for use as an adjunct in cleaning both soft hydrophilic and rigid gas permeable contact lenses using approved contact lens cleaning solutions. Examples of approved cleaning solutions indicated for use with the LENSERVER Automatic for soft hydrophilic lenses are the Allergan Soft Mate Consept-1 Cleaning and Disinfecting Solution, Allergan Soft Mate Cdrisept-2 Neutralizing and Rinsing Solution, or Spray. The LENSERVER Automatic is indicated for cleaning rigid gas permeable lenses in conjunction with approved solutions such as Allergan Gas Permeable Daily Cleaner and Allergan ComfortCare Gas Permeable Wetting and Soaking Solution.	
Technical Principle	Protein electrophoresis	Ultrasonic Cleaning	Different Note 2
Mechanism of Action	Electrical	Electro-mechanical	Different Note 3
Configuration	Cleaning Unit(Power Base) Cleaning chamber	Motorized cleaning unit Cleaning beaker	Similar Note 4
Shutdown mode	Automatic timing shutdown	Automatic timing shutdown	Same
Power	Built-in lithium battery	Dry Battery	Different Note 5
Material	Medical grade ABS	Medical grade polymethylpentene	Similar Note 6
Sterile	Non-sterile	Non-sterile	Same
Single use	No	No	Same
Environment of Use	home	home	Same

The following technological differences exist between the subject and predicate devices:

Note 1

The intended use of proposed device and predicate device are similar. The proposed device has storage function. It is expected that the proposed device has more storage functions than the predicate device, just like a contact lens case.
It will not affect the main function and intended use of the device, and indications for use of proposed device is clearly indicated in user manual and label. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

Note 2 and Note 4

The technical principle and configuration of proposed device and predicate device are different, but it will not affect the main function and the intended use of the device. They are both electrical means. And they are both compliance with electrical safety Standard. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

Note 3

The mechanism of action of proposed device and predicate device are different, but it will not affect the main function and the intended use of the device. They are both meet the related standards and requirements of physical compatibility. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

Note 5

The battery type of proposed device and predicate device are different. They are both compliance with electrical safety standard, it will not raise any safety or effectiveness issue.

Note 6

The main materials of the proposed device and predicate device are different. They are both compliance with medical requirements and standard ISO 10993-1, 10993-5, 10993-11. It will not raise any safety or effectiveness issue.

7. Non-Clinical Data

The following performance data were provided in support of the substantial equivalence determination.

7.1 Biocompatibility testing

The biocompatibility evaluation for the 3N Contact Lenses Adjunct Cleaner is conducted in accordance with the International Standard ISO10993-1 " Biological Evaluation of Medical Devices − Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The worst case of the device is considered mucosal membranes contacting for duration of less than 24 hours. And the testing included the following tests:

- Cytotoxicity Study using MTT Method
- Guinea Pig Maximization Test
- Ocular Irritation test

7.2 Software Verification and Validation

Software documentation, including verification & validation, was provided following FDA Guidance: Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices for software with a minor level of concern.

7.3 Safety and EMC

Testing was performed to verify the basic safety and essential performance of the 3N Contact Lenses Adjunct Cleaner, TN 083. The following tests were performed:
IEC 61010-1:2010+A1:2016 Safety requirements for electrical equipment for measurement, control, and laboratory use-Part1: General requirements
IEC 61326-1:2013 Electrical equipment for measurement, control and laboratory use-EMC requirements- Part 1: General requirements

7.4 Performance Testing- Bench

The following tests were performed to demonstrate that the proposed 3N contact lenses adjunct cleaner met the applicable design and performance requirements and support a determination of substantial equivalence. Where applicable, testing was done per applicable ISO and other international standards.

- **Deproteinization efficiency testing and Service life testing**

Testing was performed to verify the Protein removal effect of the 3N contact lenses adjunct cleaner. This verification test selected lenses of four kinds of materials from Johnson and Cooper Optics. After soaking in artificial tears, Ocufilcon D and Etafilcon A soft contact lenses had a large amount of protein adsorption. The protein cleaning rate was more than 92.5% with 3N contact lenses adjunct cleaner combined with care solution. However, Comfilcon A and Senofilcon A soft contact lenses have very little protein adsorption, so it is impossible to calculate the clearance effect. The protein removal rate of Ocufilcon D soft contact lens was 95% after 3N contact lenses adjunct cleaner was recycled for 0, 151 times. So the shelf life of the 3N contact lenses adjunct cleaner is 3 months.

- **Physical compatibility testing**

The testing was considerably streamlined just assessing 3 low modulus high water SCLs (>50wt% water, for example 3 commercial lenses from any of these SCL materials, hioxifilcon A, nelfilcon A or nesofilcon A, or other high water materials) with the 3N device.
Deviation of the parameters of contact lenses before and requirements after cleaned by 3N Contact

Lenses Adjunct Cleaner complies with the relevant requirements in ISO 18369-2:2017.

- Cleaning Validation was performed to demonstrate functionality is not affected after maximum number of cleaning cycles. The device was cleaned following the procedure defined in the User's Manual.

7.5 Performance Testing – Animal

This submission does not include any animal performance testing. It was determined that no such testing was required to demonstrate substantial equivalence.

7.6 Performance Testing – Clinical

This submission does not include any clinical performance testing. It was determined that no such testing was required to demonstrate substantial equivalence.

8. Conclusion

From the bench test conducted on the proposed device provided in above, the test result showed that the proposed device can meet the requirements of related standards. Therefore, it can be determined that the proposed devices are Substantially Equivalent (SE) to the predicate device, K982115.