May 15, 2020

The LifeStyle Company, Inc.
% Michael A. Siano, MA, RAC
Regulatory Affairs Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K200747
Trade/Device Name: PuriLens Plus Preservative Free Saline
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LPN, MRC
Dated: March 18, 2020
Received: March 23, 2020

Dear Michael Siano:

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)*
K200747

Device Name
PuriLens Plus Preservative Free Saline

Indications for Use *(Describe)*
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.

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

PuriLens Plus Preservative Free Saline

1. Submission Sponsor

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USA
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Email: toms@well.com
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2. Submission Correspondent

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Contact: Michael A. Siano
Title: Regulatory Affairs Consultant

3. Date Prepared

3/18/2020

4. Device Identification

Trade/Proprietary Name:	PuriLens Plus Preservative Free Saline
Common/Usual Name:	Accessories, Soft Lens Products
	Products, Contact Lens Care, Rigid Gas Permeable
Regulation Number:	886.5918, 886.5928
Product Code:	MRC, LPN
Class:	Class 2
Classification Panel:	Ophthalmic

5. Legally Marketed Predicate Device(s)

The LifeStyle Company, Inc., claims substantial equivalence to the Purilens Saline Solution (K002319), Purilens, Inc., in terms of intended use and technological characteristics.

6. Indication for Use

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.

7. Device Description

The PuriLens Plus Preservative Free Saline is a sterile, buffered saline solution for rinsing and storing contact lenses. The solution is buffered to roughly physiological pH and has an osmolarity similar to that of human tears. The product is sold over-the-counter in various packaging configurations.

The current generation of the product, Purilens Saline Solution, was cleared under K002319 in 2000, and has been legally marketed in the US since that time. This 510(k) application is to expand the indications for use to include use with rigid gas permeable lenses. There is no change in the device design, formulation, or manufacturing. The labeling will be revised with the new indications.

8. Substantial Equivalence Discussion

The following table compares the PuriLens Plus Preservative Free Saline to the predicate device with respect to intended use, technological characteristics, materials, and performance, forming the basis for the determination of substantial equivalence.

Table 1. Substantial Equivalence Comparison

Attribute	PuriLens Plus Preservative Free Saline	Purilens Saline Solution
Manufacturer	The LifeStyle Company, Inc.	Purilens, Inc.
510(k) Number		K002319
Product Code	LPN, MRC	LPN
Class	2	2
Classification Panel	Ophthalmic	Ophthalmic
Regulation Number	886.5918 886.5928	886.5928
Intended Use	Contact lens solution	Contact lens solution
Indications for Use	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.	Purilens Saline Solution is indicated for the cleaning and disinfecting of contact lenses by means of use in a Purilens Electronic Lens Care System. Lenses may by stored in disinfected solution for a period of 24 hours following the cleaning and disinfecting.
OTC/Rx	OTC	OTC
Volume	120 mL, 60 mL	120 mL

Preservative-Free	Yes	Yes
Container Usage	Multi-use	Multi-use
Sterility	Sterile	Sterile
Materials (container)	Plastic resin container with puncture, re-usable cap	Plastic resin container with puncture, re-usable cap
Biocompatibility	Evaluated in accordance with FDA Guidance *Premarket Notification (510(K)) Guidance Document for Contact Lens Care Products*	Evaluated in accordance with FDA Guidance *Premarket Notification (510(K)) Guidance Document for Contact Lens Care Products*

9. Equivalence Discussion

Some differences exist between the subject and predicate. None of the minor differences noted raise different questions of safety and effectiveness.

10. Non-Clinical Performance Data

Because the subject is identical to the predicate in terms of formulation, manufacturing, and packaging, no bench-testing is required to demonstrate substantial equivalence.

11. Statement of Substantial Equivalence

The PuriLens Plus Preservative-Free Saline has the same intended use and technological characteristics as the Purilens Saline Solution. Therefore, the PuriLens Plus Preservative-Free Saline is substantially equivalent to the predicate device.