April 27, 2021

VP Optics
℅ Bret Andre
Principal Consultant
EyeReg Consulting Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K210609
Trade/Device Name: AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: February 24, 2021
Received: March 1, 2021

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)*
K210609

Device Name
AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens

Indications for Use *(Describe)*
The AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia and hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 3.00 diopters or less. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eye.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system. Eye care practitioners may prescribe the lens for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each removal.

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: **K210609**

I. SUBMITTER

Date Prepared: February 24th, 2021

Name: **VP OPTICS**
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Daejeon, Yuseong-gu, Korea

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

II. DEVICE

Trade Name: **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens**

Common Name: Contact Lens, Daily Wear

Classification Name: Soft (hydrophilic) Contact Lens (21 CFR 886.5925)

Regulatory Class: Class II

Product Code: LPL; MVN

Purpose of 510(k) Submission:

~ New Device ~

III. PREDICATE DEVICE

The **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens** is substantially equivalent to the following predicate device:

- "**Neo Cosmo (Polymacon) Soft (Hydrophilic) Contact Lens"**
  By NEO VISION CO., LTD.
  510(k) number; **K142275**
  Primary Predicate

IV. DEVICE DESCRIPTION

The **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens** is a hydrophilic polymer of 2-hydroximethyl methacrylate (HEMA) cross-linked with Ethylene glycol dimethylacrylate (EGDMA) and water. When hydrated the lens consists of 62.0% polymacon and 38.0% water by weight when immersed in saline solution. The (polymacon) name has been adopted by the United States Adopted Names Council (USAN).

The **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lenses** are available tinted for visibility or color printed to enhance or alter the apparent color of the eye. The lenses are processed to incorporate the 'listed' color additives and contain only the amount of the additive needed to accomplish the intended coloring effect. The lenses contain one or a combination of one or more of the following 'listed' color additives:

Color Additive	Listing
Titanium Dioxide	21 CFR § 73.3126
Iron Oxide	21 CFR § 73.3125
D&C Yellow No. 10	21 CFR § 73.3110
C.I. Pigment Violet 23	21 CFR § 73.3107
C.I. Pigment Green 7	21 CFR § 73.3124

When producing the color lenses, the manufacturing process changes the specifications to the clear contact lens by pad-printing the color pigment(s)—entrapping the colorants in the interpenetrating network of the contact lens material in a location that corresponds to the iris. The color pigments used are not removed by lens handling and cleaning/disinfecting procedures. Except for affecting the amount of light transmittance through the lens, the coloring process does not alter the original characteristics of the pre-tinted lens.

The **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens** is manufactured in sphere and toric design configurations. The material properties and available parameters of the finished lenses are as follows:

Parameter	Range	Tolerance
Chord Diameter	13.5 mm to 14.5 mm	±0.20 mm
Center Thickness	0.03 mm to 0.50 mm	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	8.30 mm to 9.0 mm	±0.20 mm
Back Vertex Power (F'v)	+10.00D to -10.00D (in 0.25D steps)	When 0.00 < |F'v| ≤ 10.00 D → ±0.25 D
Cylinder Power (F'c)	-0.75D to -2.75D (in 0.25D steps)	When 0.00 < |F'c| ≤ 2.00 D → ±0.25 D When 2.00 < |F'c| ≤ 4.00 D → ±0.37 D
Cylinder Axis	10° to 180° (in 10° steps)	When 0.00 < |F'c| ≤ 1.50 D → ± 8° When|F'c| > 1.50 D → ± 5°
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10^{-11}(cm^2/sec)(mlO2)/(ml x mmHg))	9.77	±20%
Light Transmission (@ 380-780nm)	>90%	±5%
Water Content	38%	±2%
Refractive Index	1.428 (hydrated)	±0.005

V. INDICATIONS FOR USE

The **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens** is indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia and hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 3.00 diopters or less. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eye.

Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system. Eye care practitioners may prescribe the lens for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each removal.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens** is substantially equivalent to the primary predicate device identified (K142275) regarding the following features:

- USAN contact lens material (polymacon)
- FDA category - Group I
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- Actions
- Cast molded production method
- Injection molded polypropylene blister packaging

The following matrix illustrates the production method, lens function and material characteristics of the **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens**, as well as the predicate device.

	VP Optics Aquasplash (Subject Device)	**NEO VISION CO., LTD. Neo Cosmo (K142275)**
Intended Use	Daily wear, Soft (hydrophilic) contact lens	Daily wear, Soft (hydrophilic) contact lens
Actions	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina	The contact lenses act as a refractive medium that focus light rays from near and distant objects on the retina
FDA Classification	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)	Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
FDA Group	FDA Group 1 (<50% H_2O, non-ionic polymer)	FDA Group 1 (<50% H_2O, non-ionic polymer)
Production Method	Fully molded	Fully molded
USAN name	polymacon	polymacon
Water Content (%)	38±2%	38±2%
Oxygen Permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x mmHg @ 35°C)) (revised Fatt method)	9.77	9.77
Refractive Index (hydrated)	1.43	1.43
Modulus (MPa)	0.350	0.350
UV Blocker	No	No
Manufacturing	Cast-Molded	Cast-Molded
Pad-Printed Color	Yes	Yes

	Indications for Use
VP Optics Aquasplash (Subject Device)	The **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens** is indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia and hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 3.00 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lens for frequent/planned replacement wear, with cleaning disinfection and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system. Eye care practitioners may prescribe the lens for single use daily disposable wear. When prescribed for daily disposable wear the lens is to be discarded after each removal.
NEO VISION CO., LTD. Neo Cosmo (K142275)	The Neo Cosmo (Polymacon) Soft (hydrophilic) Contact Lens is indicated for daily wear for the correction of visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia or hyperopia. The lens may be worn by persons who exhibit refractive astigmatism of 0.50 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lens frequent replacement wear with cleaning, disinfecting and schedule replacement. The lens may be disinfected using a chemical (not heat) lens care system only.

VII. PERFORMANCE DATA

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

Non-Clinical Performance Testing

Non-clinical testing was conducted to support the claim that the **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens** is substantially equivalent to the currently marketed predicate device. A summary of the results from the non-clinical studies is presented below.

Lens Design/Manufacturing Verification:

Bench testing was performed to verify the ability to manufacture the AQUASPLASH (polymacon) finished toric contact lenses to a variety of prescribed parameters within manufacturing tolerances.

Clinical Testing

Clinical testing is not required. The clinical performance of soft (hydrophilic) contact lenses manufactured from polymacon materials has been demonstrated previously.

VIII. CONCLUSIONS

Validity of Scientific Data

Laboratories under Good Laboratory Practice regulations conducted toxicology and microbiology studies following scientific protocols. The data were determined to be scientifically valid under 21 CFR 860.7.

Substantial Equivalence

Information presented in this Premarket Notification establishes that the **AQUASPLASH (Polymacon) Soft (Hydrophilic) Daily Wear Contact Lens** is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the proposed indication.

Risks and Benefits

The risks of the subject device are the same as those normally attributed to the wearing of soft (hydrophilic) daily wear contact lenses. The benefits to the patient are the same as those for other soft (hydrophilic) daily wear contact lenses.