March 5, 2019

Eyemed Technologies S.r.l.
Mr. Franco Ceravolo
Managing Director
Via al Boscaccio 3
21011 Casorate Sempione (VA) - Italy

Re: K181656
Trade/Device Name: ADORE (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Tinted/color)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: December 27, 2018
Received: January 24, 2019

Dear Mr. Ceravolo:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

J Angelo Green -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*
K181656

Device Name
ADORE (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Tinted/color)

Indications for Use *(Describe)*
The ADORE (polymacon) Spherical Soft Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia or hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye. Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.
Frequent/Planned Replacement Wear:
Eyecare practitioners may prescribe any of the above lenses 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.
Disposable Wear:
Eyecare practitioners may prescribe any of the above lenses for Daily Disposable Wear. When Prescribed for Daily Disposable Wear the lenses are not to be used with disinfecting systems as they are to be discarded after a single 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510 (k) SUMMARY

SUBMITTER INFORMATION

A. Company Name: Eyemed Technologies S.r.l.

B. Company Address: Via al Boscaccio 3
21011 Casorate Sempione (VA) - Italy

C. Company Phone: +39-0331201024
Company Fax: +39-0331287154
Company e-mail: affair@eyemed.it

D. Contact person: Mr. Franco Ceravolo
Managing Director
Eyemed Technologies S.r.l.

E. Date Summary Prepared: May 18, 2018

DEVICE IDENTIFICATION

A. Common Name: Lenses, Soft Contact, Daily Wear

B. Trade/Proprietary Name: ADORE (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Tinted/color)

C. Device Classification: Class II

D. Product Code: LPL; MVN

E. Classification Name: Soft (hydrophilic) Contact Lens

E. Regulation Number: 21 CFR 886.5925

LEGALLY MARKETED PREDICATE DEVICE

Predicate device	510 (k) Holder	510 (k) No.	Date cleared
ChicView (Polymacon) Daily Wear Soft (Hydrophilic) Contact Lenses (Tinted/Color)	JOOWON INNOVATION CO., LTD.	K161098	August 22, 2016

DEVICE DESCRIPTION

The ADORE soft contact lenses are hemispherical shells with molded spherical base curves and molded front surfaces. The ADORE soft contact lenses are fabricated from polymacon, which has been adopted by the United States Adopted Names Council (USAN). The hydrophilic nature of this material allows the lens to become soft and pliable when immersed in an aqueous solution.

The nonionic lens material, (polymacon) is a hydrophilic polymer of 2-Hydroxyethyl methacrylate (2-HEMA) and cross-linked with ethylene glycol dimethacrylate (EGDMA), plus an initiator. The co-polymer consists of 62% polymacon and 38% water by weight when immersed in saline solution.

ADORE lenses are available clear, tinted for visibility/handling, and tinted to enhance or alter the apparent color of the eye. Tinted or color lens designs may be distributed under unique or "private label" trade names. ADORE lenses are available in gray, green, yellow, hazel, blue, white or black - which are tinted with one or a combination of one or more of the following 'listed' color additives:

Name of Colorant	Listing
D&C Yellow 10	21 CFR 74.3710
Titanium Dioxide	21 CFR 73.3126
Iron Oxide (Red)	21 CFR 73.3125
D&C Green No. 6	21 CFR 74.3206
Reactive Blue 19	21 CFR 73.3127
C.I. Reactive Black 5	21 CFR 73.3121

Lenses that contain a unique tinting pattern are subsequently processed to incorporate the 'listed' color additives, and contain only the amount of color additive needed to accomplish the intended coloring effect. When producing the tinted or color lenses, the manufacturing process alters and/or changes the specifications to the clear version of a contact lens by entrapment of the listed color additives in the center of the contact lens (surrounded by layers of contact lens material) in a location that corresponds to the iris. The color additives 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 color lens tinting pattern has a minimum Clear Pupil diameter of 6.0 mm.

In the hydrated state, the lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus forming a transparent or colored optical surface. The (polymacon) soft hydrophilic contact lens has a spherical back surface. The hydrophilic properties of the lens require that it be maintained in a fully hydrated state in a solution compatible with the eye. If the lens dries out, it will become hard and appear somewhat warped; however, it will return to its proper configuration when completely rehydrated in the proper storage solution.

The physical properties of the lens are:

Refractive Index	1.435
Light Transmission (clear)	greater than 98%
Light Transmission (tinted/color)	greater than 98% (at clear region corresponding to pupil, minimum 6.0 mm diameter); Opaque or 0-10% (at tinted region corresponding to iris)
Surface Character	hydrophilic
Water Content	38±2%
Specific Gravity	1.17 (hydrated)
Oxygen Permeability	$11.15x10^{-11}$ (cm^2/sec)(ml O_2)(ml x mm Hg @ 35°C) (revised Fatt method)

The hydrophilic characteristics allow aqueous solution to enter the lens, and in its fully hydrated state the lens is approximately 38% water by weight. ADORE (polymacon) Spherical Soft Contact lenses are available in the spherical configuration with the following features and properties:

Chord Diameter	14.00 mm
Center Thickness	0.08 mm (to – 3.00D)
Base Curve	8.6 mm
Power Range	From D. 0.00 to D. -16.00 (from D. -5.00 a D. -16.00 with 0.50 steps) From D. +0.25 to D. +10.00 (from D. +5.00 to D. +10.00 with 0.50 steps)
Colors available	Grey, Hazel, Yellow, Blue, White, Green

ADORE lenses are supplied sterile in saline solution containing blister packages with a base made from polypropylene and a laminated foil seal on top. Blister package labeling is printed with the appropriate lot numbering, expiration dating, and lens parameter identification. Expiration dating has been established based on studies of product stability, package integrity, and validation of the sterilization process.

INDICATIONS FOR USE STATEMENT

The ADORE (polymacon) Spherical Soft Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not aphakic persons with non-diseased eyes. The lens may be worn by persons who exhibit refractive astigmatism of 0.75 diopters or less where the astigmatism does not interfere with visual acuity. The lens is available clear or tinted and may be used to enhance or alter the apparent color of the eye.
Daily wear replacement schedules may vary from patient to patient and should be decided by eyecare practitioners in consultation with their patients.

Frequent/Planned Replacement Wear:
Eyecare practitioners may prescribe any of the above lenses 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.

Disposable Wear:
Eyecare practitioners may prescribe any of the above lenses for Daily Disposable Wear. When Prescribed for Daily Disposable Wear the lenses are not to be used with disinfecting systems as they are to be discarded after a single use.

TESTING

Non-clinical Testing

A series of in vitro and in vivo preclinical toxicology and biocompatibility tests were performed to assess the safety and effectiveness of the **ADORE** (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses. All non-clinical toxicology tests were conducted in accordance with the GLP regulation. All other testing was conducted according to valid scientific protocols.

Test results of the non-clinical testing on the ADORE (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses demonstrate that:

- Lenses supplied in blister packages are sterile for the indicated shelflife,
- The packaging material and extracts are not toxic and not irritating, and
- Lens physical and material properties are consistent with currently marketed lenses.

Clinical Data

The clinical performance of the (polymacon) lens material has been previously established, and therefore was not required for this 510(k).

CONCLUSIONS DRAWN FROM STUDIES

Validity of Scientific Data

Several laboratories under Good Laboratory Practice regulations conducted toxicology studies, microbiology, chemistry, shelf-life stability studies and followed 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 ADORE, (polymacon) Soft Contact Lenses for Daily Wear is as safe and effective as the predicate device when used in accordance with the labeled directions for use and for the requested indication.

Risks and Benefits

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

SUBSTANTIAL EQUIVALENCE

The ADORE Soft Contact Lens will be manufactured according to specified process controls and a cGMP quality assurance program currently in place. The established safety profile (pre-clinical toxicology and manufacturing/chemistry data) of the ADORE contact lens material is equivalent to the predicate devices identified previously. Being similar with respect to indications for use, materials, physical construction and safety & effectiveness to the predicate devices, this meets the requirements per section 510(k) of the act regarding substantial equivalence and does not raise different questions of safety and effectiveness than the predicate device identified above.

The following matrix illustrates the equivalencies of the ADORE Soft (hydrophilic) Contact Lens, as well as the substantial equivalent predicate devices.

PREDICATE DEVICES COMPARISON CHART

Table 1

	EYEMED TECHNOLOGIES S.R.L. ADORE New device	**JOOWON INNOVATION CO., LTD.** CHICVIEW Predicate device
"K" NUMBERS	**K_____**	**K161098**
Proprietary name	**ADORE**	**CHICVIEW**
CFR Section	886.5925	886.5925
Pro-code	LPL; MVN	LPL; MVN
Classification name	Daily Wear, Soft (hydrophilic) Contact Lens (Class II)	Daily Wear, Soft (hydrophilic) Contact Lens (Class II)
Intended / Indications for use	Indicated for daily wear for the correction of refractive ametropia (myopia and hyperopia) in aphakic and not aphakic persons with non-diseased eyes and/or possesses refractive astigmatism not exceeding 0.75 diopters. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eye.	Indicated for daily wear for the correction of visual acuity in aphakic and not aphakic persons with nondiseased eyes with myopia or hyperopia and/or possesses refractive astigmatism not exceeding 0.75 diopters. The lens is available clear or colored and may be used to enhance or alter the apparent color of the eye.
Functionality	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
Production method	Fully-molded	Fully-molded
USAN name	Polymacon	Polymacon
Water content	38±2%	38±2%
Light trasmittance	>98%	>98%
Refraction Index	1,435	1,435
Oxygen permeability	$11.15x10^{-11}$ (cm^2/sec)(ml O_2)(ml x mm Hg @ 35°C) (revised Fatt method)	$11.15x10^{-11}$ (cm^2/sec)(ml O_2)(ml x mm Hg @ 35°C) (revised Fatt method)
Sterilization	Steam Validated Autoclave	Steam Validated Autoclave
Specific Gravity	1.17 (hydrated)	1.17 (hydrated)