August 5, 2022

DK Medivision Co., Ltd.
℅ Bret Andre
Principal Consultant
EyeReg Consulting Inc.
6119 Canter Lane
West Linn, OR 97068

Re: K220045
Trade/Device Name: TREVUES (polymacon) 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: June 28, 2022
Received: July 1, 2022

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)*
K220045

Device Name
TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)

Indications for Use *(Describe)*
The TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color) are indicated for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 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.

The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a frequent replacement program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting system.

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 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: **K220045**

I. SUBMITTER

Date Prepared: June 25th, 2022

Name: **DK Medivision Co., Ltd.**
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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: **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)**

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 **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** are substantially equivalent to the following predicate device(s):

- "**Eye Secret 38 UV Aspheric (polymacon) Soft (hydrophilic) Contact Lens"**
  By YUNG SHENG OPTICAL
  510(k) number; **K132854**
  Primary Predicate
- "**ChicView (Polymacon) Daily Wear Soft (Hydrophilic) Contact Lenses (Tinted/Color)**"
  By JOOWON INNOVATION CO., LTD.
  510(k) number; **K161098**
  Reference Predicate

IV. DEVICE DESCRIPTION

The **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** are manufactured using the cast molding method. The hydrophilic characteristics allow aqueous solutions to enter the lens. The lenses are fabricated from polymacon, which is a random copolymer of 2-hydroxyethyl methacrylate (HEMA) crosslinked with ethylene glycol dimethacrylate (EGDMA). The co-polymer consists of 62% polymacon and 38% water by weight when immersed in saline solution. The polymacon name has been adopted by the United States Adopted Names Council (USAN).

The **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** are available clear, tinted for visibility, or tinted 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
Iron Oxide	21 CFR § 73.3125
C.I. Reactive Blue No.4	21 CFR § 73.3121
Reactive Black 5	21 CFR § 73.3127
Titanium Dioxide	21 CFR § 73.3126

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 tinting pattern has a clear pupil diameter of 6.0 mm.
The **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** incorporate a UV absorbing monomer. The lenses block >95% in the UVB range (280nm - 315nm), and >50% in the UVA range (316nm - 380nm).

The **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** are manufactured in an aspheric design configuration. The material properties and available parameters of the finished lenses are as follows:

Parameter	Range	Tolerance*
Chord Diameter	11.00 mm to 15.00 mm	±0.20 mm
Center Thickness	0.05 mm to 0.15 mm	When ≤ 0.10 mm → ±0.010 mm + 10% When > 0.10 mm → ±0.015 mm + 5%
Base Curve	7.00 mm to 10.0 mm	±0.20 mm
Back Vertex Power (F'v)	-0.50 D to -12.00D (in 0.25D steps)	When 0.00 < |F'v| ≤ 10.00 D → ±0.25 D When 10.00 < |F'v| ≤ 20.00 D → ±0.50 D
Surface Appearance	-	Lenses should be clear with no surface defect
Oxygen Permeability (x 10^{-11}(cm^2/sec)(mlO2)/(ml x mmHg))	11.12	±20%
Light Transmission - Tinted (@ 380-780nm)	95%	±5%
Ultraviolet Radiation Transmittance	< 5 % T_{UVB} < 50 % T_{UVA}	$T_{UVB\ (280\ to\ 315\ nm)} < 0.05T_V$ $T_{UVA\ (316\ to\ 380\ nm)} < 0.50T_V$
Water Content	38%	±2%
Refractive Index	1.440 (hydrated)	±0.005

* ISO 18369-2:2017 Ophthalmic optics — Contact lenses — Part 2: Tolerances

V. INDICATIONS FOR USE

The **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** are indicated for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 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.

The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a frequent replacement program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting system.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE DEVICE

The **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** are substantially equivalent to the predicate devices identified (K132854 and K161098) in terms of the following:

- USAN contact lens material (polymacon)
- FDA Group 1 (<50% H_2O, non-ionic polymer)
- FDA classification – Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
- Intended use – daily wear contact lenses
- Actions
- Indications for use
- UV absorber
- Cast molded production method
- Pad-printing contact lens tinting method (reference predicate K161098)

The following matrix illustrates the production method, lens function and material characteristics of the **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)**, as well as the predicate devices.

	DK Medivision TREVUES (Subject Device)	**Yung Sheng Optical Eyesecret 38 UV (K132854)**	**Joowon Innovation ChicView (K161098)**
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	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)	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)	FDA Group 1 (<50% H_2O, non-ionic polymer)
Production Method	Fully molded	Fully molded	Fully molded
USAN name	polymacon	polymacon	polymacon
Water Content (%)	38±2%	38±2%	38±2%
Oxygen Permeability x 10^{-11} (cm^2/sec)(mlO_2)/(ml x mmHg @ 35°C)) (revised Fatt method)	11.12	13.35	11.15
Refractive Index (hydrated)	1.440	1.440	1.435
UV Blocker	Yes	Yes	No
Pad-Printed Tinting	Yes	No	Yes
Sterilization Process	Steam sterilization	Steam sterilization	Steam sterilization
Packaging	Blister	Blister	Blister

	Indications for Use
DK Medivision TREVUES (Subject Device)	The TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color) are indicated for the correction of refractive ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters 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. The eye care professionals may prescribe the lens for single use daily disposable or daily wear in a Frequent Replacement Program. As prescribed for planned replacement, the lens should be disinfected using a chemical or hydrogen peroxide disinfecting system.
Yung Sheng Optical Eyesecret 38 UV (K132854)	The Eye Secret 38 UV Apsheric (polymacon) Soft (hydrophilic) Contact Lenses for Daily Wear are indicated for the correction of ametropia (myopia) in aphakic and not-aphakic persons with non-diseased eyes. The lenses may be worn by persons who exhibit astigmatism of 2.00 diopters or less that does not interfere with visual acuity.
Joowon Innovation ChicView (K161098)	The ChicView (polymacon) Spherical Soft Contact Lenses for daily wear are indicated for the correction of visual acuity in aphakic and not aphakic persons with non-diseased eyes with myopia or hyperopia. 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.

VII. PERFORMANCE DATA

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

Non-clinical Testing

A series of preclinical testing was performed to demonstrate the safety and effectiveness of the **TREVUES (polymacon)** finished contact lenses. The results support the claim that the **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** are substantially equivalent to the currently marketed predicate devices. A summary of the results from the preclinical studies is presented below.

Toxicology:

All non-clinical toxicology tests were conducted in accordance with the GLP regulation.

- In-Vitro Cytotoxicity: Cytotoxicity testing was performed in accordance with ISO 10993-5 with results indicating that the finished lenses and packaging materials are non-toxic.
- Systemic Toxicity: The finished lenses and packaging materials meet the requirements of the systemic injection test in accordance with ISO 10993-11 and are considered non-toxic.
- Acute Ocular Irritation: Acute ocular irritation test was performed in accordance with ISO 10993-10 and produced no ocular irritation for the finished lenses and packaging materials.

Shelf Life:

Testing was performed to evaluate the stability, sterility, and package integrity of the **TREVUES (polymacon)** finished contact lenses over the duration of the labeled expiration date. The data presented supports substantial equivalence of the contact lenses to the already marketed predicate devices.

Physicochemical & Mechanical Properties:

The following tests were completed to verify substantial equivalence to predicate devices: refractive index, water content, Dk, % transmission (visible & UV), tensile strength, modulus, % elongation to break, specific gravity and polymerization residuals. Results of physicochemical and mechanical property testing demonstrate consistency of the material properties between the **TREVUES (polymacon)** contact lenses and the predicate devices.

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 conducted biocompatiblity, microbiology, and shelf-life stability 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 **TREVUES (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)** are 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.