July 30, 2025

E.O.S Co., Ltd.
% Sanglok Lee
Manager
Wise Company Inc.
#1107, #1108, 204, Gasan digital 1-ro, Geumcheon-gu
Seoul, 08502
Korea, South

Re: K242855
Trade/Device Name: P-CON (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
Dated: June 16, 2025
Received: June 16, 2025

Dear Sanglok Lee:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

J. Angelo Green, Ph.D.
Assistant Director
DHT1A: Division of Ophthalmic Devices
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Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242855

Device Name

P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)

Indications for Use *(Describe)*
P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color) for daily wear are spherical lenses indicated for the correction of refractive error in not-aphakic persons with otherwise non-diseased eyes with myopia ranging from -0.00 diopters to -10.00 diopters.

The lenses may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lenses are available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Eye care practitioners may prescribe the lenses in a frequent/planned replacement program with cleaning, disinfection, and scheduled replacement. The lenses are intended for daily wear and are to be replaced every three months (quarterly). When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical 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.

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.

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"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."

The assigned 510(k) Number: K242855

01. Date of Submission: 2025.07.18

02. Applicant

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03. Submission Correspondent

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04. Subject Device Identification

Trade Name: P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color)
Common Name: Contact Lens, Daily Wear
Classification Name: Soft (hydrophilic) Contact Lens (21 CFR 886.5925)
Product Code: LPL
Panel: Ophthalmic
Regulation Number: 886.5925
Device Class: Class II

05. Indication for use

P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color) for daily wear are spherical lenses indicated for the correction of refractive error in not-aphakic persons with otherwise non-diseased eyes with myopia ranging from -0.00 diopters to -10.00 diopters.

The lenses may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lenses are available clear or tinted and may be used to enhance or alter the apparent color of the eye.

Eye care practitioners may prescribe the lenses in a frequent/planned replacement program with cleaning, disinfection, and scheduled replacement. The lenses are intended for daily wear and are to be replaced every three months (quarterly). When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

06. Predicate devices

Predicate device
510(k) Number: K221517
Device Name: POLYVUE (polymacon) Soft (hydrophilic) Contact Lens, POLYVUE COLOR (polymacon) Soft (hydrophilic) Contact Lens
Manufacturer: Interojo Inc.

07. Device Description

The P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color) is 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 0.9% saline solution. The polymacon name has been adopted by the United States Adopted Names Council (USAN).

The P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color) is available clear or tinted for visibility using phthalocyanine blue, tinted in unique pattern to enhance or alter the apparent color of the eye. Each unique patterns may be distributed under unique or "private label" trade names. 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
C.I Reactive Black 5	21 CFR 73.3127
Titanium Dioxide (TiO_2)	21 CFR 73.3126
Carbazole Violet (i.e.,C.I Pigment Violet 23)	21 CFR 73.3107
Phthalocyanine green (i.e.,C.I PIgment Green 7)	21 CFR 73.3124
D&C Yellow No. 10	21 CFR 74.3710
D&C Red No. 17	21 CFR 74.3230
[Phthalocyaninato (2-)] Copper (i.e.,C.I PIgment Blue 15)	21 CFR 74.3045

When producing the color lenses, the manufacturing process changes the specifications of the clear 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 clear, pre-tinted lens.

Eye care practitioners may prescribe the lenses in a frequent/planned replacement program with cleaning, disinfection, and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.

08. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the subject device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the subject device complies with the following standards:

Biocompatibility:

Biocompatibility testing was conducted in accordance with the ISO 10993 series and GLP (Good Laboratory Practice) regulations. Packaging material testing was conducted using the big blister configuration.
The following tests were performed:

• Cytotoxicity: Testing conducted in accordance with ISO 10993-5 confirmed that both the finished lens extracts and packaging material extracts (Big blister and Aluminum foil seal) were non-cytotoxic.

• Sensitization: Testing conducted in accordance with ISO 10993-10 confirmed that the lens extracts did not induce sensitization.

• Acute Ocular Irritation: Testing conducted in accordance with ISO 10993-23 confirmed that both the finished lens extracts and packaging material extracts (Big blister and Aluminum foil seal) were non-irritating.

• Acute Systemic Toxicity (mouse): Testing conducted in accordance with ISO 10993-11 confirmed that both the finished lens extracts and packaging material extracts (Big blister and Aluminum foil seal) were non-toxic.

• Material-Mediated Pyrogenicity (rabbit): Testing conducted in accordance with ISO 10993-11 confirmed that the finished lenses did not induce a pyrogenic response.

• Determination of Biocompatibility of Contact Lenses in Rabbit Eyes: Testing conducted in accordance with ISO 9394 confirmed that the finished lenses were non-toxic.

• Primary Packaging Biocompatibility: Cytotoxicity, acute systemic toxicity, and ocular irritation testing were conducted on the big blister and foil seal (without the lens), and all packaging components were found to be non-cytotoxic, non-irritating, and non-toxic.

The small blister configuration utilizes the same raw materials, laminate structure, and manufacturing process as the big blister. Given that the big blister has a larger surface area and is subject to a greater

amount of ink and processing stress, it is considered the worst-case configuration from a biocompatibility standpoint. Therefore, the biocompatibility testing performed on the big blister is scientifically justified as representative of the small blister configuration as well. No additional biocompatibility testing was conducted on the small blister.

Shelf Life:
Testing was performed to evaluate the stability, sterility, and package integrity of The P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color) finished contact lenses over the duration of the labeled expiration date. The data shows the 5 years validity shelf life of the subject device.

Physicochemical & Mechanical Properties:
The following tests were completed to verify Physicochemical & Mechanical Properties: Shape and Appearance, Diameter, Basecurve, Center Thickness, Power, Visible light transmittance, Contact angle, Water contents, Oxygen permeability, Refractive Index, Specific Gravity, pH, Osmolality.

09. Substantially Equivalent Conclusion

Table 1: Substantial Equivalence Comparison

Product Name	SUBJECT Device	PREDICATE Device	Equivalence Discussion
510(k) number	Not assigned yet	K221517	
Product code	LPL	LPL	-
Regulatory class	Class II	Class II	-
Regulation Number	21 CFR 886.5925	21 CFR 886.5925	-
Intended use	P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color) for daily wear are indicated for the correction of refractive error in not-aphakic persons with otherwise non-diseased eyes with myopia. The lenses may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lenses are available clear or tinted and may be used to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lenses in a frequent/planned replacement program with cleaning, disinfection, and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.	The POLYVUE and POLYVUE COLOR (polymacon) ASPHERIC Soft (hydrophilic) Contact Lenses for daily wear are indicated for the correction of refractive error in not-aphakic persons with otherwise non-diseased eyes with myopia or hyperopia and early presbyopia up to 1.25 diopters. The lenses may be worn by persons who exhibit refractive astigmatism of 1.50 diopters or less where the astigmatism does not interfere with visual acuity. The lenses are available clear or tinted and may be used to enhance or alter the apparent color of the eye. Eye care practitioners may prescribe the lenses in a frequent/planned replacement program with cleaning, disinfection, and scheduled replacement. When prescribed for frequent/planned replacement wear, the lens may be disinfected using a chemical disinfecting system.	The intended use of the SUBJECT Device is equivalent to those of the PREDICATE because all of them correct visual acuity in aphakic and non-aphakic persons with non-diseased eyes with myopia. All the devices primarily correct myopia and handle astigmatism within set limits, making their intended uses fundamentally the same.
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	Equivalent
FDA Group	FDA Group 1 (<50% H 2O, non-ionic polymer)	FDA Group 1 (<50% H 2O, non-ionic polymer)	Equivalent
Production Method	Fully molded	Fully molded	Equivalent

Product Name	SUBJECT Device	PREDICATE Device	Equivalence Discussion
USAN name	polymacon	polymacon	Equivalent
Water Content (%)	38±2%	38±2%	Equivalent
Oxygen Permeability x 10-11 (cm2/sec)(mlO2)/(ml x mmHg @ 35°C)) (revised Fatt method)	9.40± 20%	10.26± 20%	Although there are differences, all values are within the criteria specified in FDA guidance, 'Soft (Hydrophilic) Daily Wear Contact Lenses – Performance Criteria for Safety and Performance Based Pathway' on March 28, 2023, making them equivalent.
Specific Gravity	1.124 ± 0.0371	*Not specified*	
Refractive Index (hydrated)	1.437 ± 0.005	1.438 ± 0.005	
UV Blocker	No	No	Equivalent
Pad-Printed Tinting	Yes	Yes	Equivalent
Primary Packaging	Blister pack with Aluminum foil seal (Small and Big)	blister base, foil seal	Equivalent
Sterilization Method	Steam sterilization	Steam sterilization	Equivalent

The subject device, The P-CON (polymacon) Soft (hydrophilic) Contact Lenses (Tinted, Color), is determined to be Substantially Equivalent **(SE)** to the predicate device, K221517, in respect of safety and effectiveness.