March 20, 2025

Hunan Haipuming Technology Co., Ltd.
% Grace Liu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518000
China

Re: K241884
Trade/Device Name: HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens (HPM38)
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: February 13, 2025
Received: February 13, 2025

Dear Grace Liu:

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
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices
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.

Submission Number *(if known)*

K241884

Device Name

HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens (HPM38)

Indications for Use *(Describe)*

HPM38 (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens is indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia. 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 tinted and 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.

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.

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.

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.

510(k) Summary - K241884

1. Contact Details

1.1 Applicant information

Applicant Name	Hunan Haipuming Technology Co., Ltd.
Address	The Intersection of Chuangye Avenue and Lvting Avenue, Dahetang Sub-district Office, Shaodong City, Shaoyang City, Hunan Province, China
Contact person	Zhang Mingxuan
Phone No.	+86-739-2712889
	+86-18107399879
E-mail	164059332@qq.com
Date Prepared	2025.03.14

1.2 Submission Correspondent

	Shenzhen Joyantech Consulting Co., Ltd. 1713A, 17th Floor, Block A, Zhongguan Times Square, Nanshan District, Shenzhen, Guangdong Province, China
Phone No.	+86-755-86069197
Contact person	Grace Liu
Contact person's e-mail	grace@cefda.com
Website	http://www.cefda.com

2. Device Information

Trade name	HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens (HPM38)
Common name	Soft (Hydrophilic) Contact Lens
Classification	II
Classification name	Lenses, Soft Contact, Daily Wear
Product code	LPL, MVN
Regulation No.	21 CFR 886.5925

3. Legally Marketed Predicate Device

Trade Name	Neo Cosmo (polymacon) Soft (hydrophilic) Contact Lens
510(k) Number	K142275
Product Code	LPL
Manufacturer	Neo Vision Co., Ltd.

The predicate device has not been subject to a design-related recall.

4. Device Description

HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens is a spherical lens. It is fabricated from

polymacon which has been adopted by the United Stated 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 lens material, polymacon, is a hydrophilic polymer of 2-hydroxyethyl methacrylate (HEMA) cross-linked with ethylene glycol dimethacrylate (EGDMA), initiated by 2, 2'-azobisisobutyronitrile (AIBN). The lens consists of 62% polymacon and 38% water by weight when immersed in standard saline solution.

HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens is available cosmetic tinted to enhance or alter the apparent color of the eye. It is tinted in an annular pattern, providing a clear optic zone, using a combination of one or more of the following 'listed' color additives:

Color additive	**Listing No.**
Reactive black 5	21 CFR 73.3121
Titanium dioxide	21 CFR 73.3126
Iron oxides	21 CFR 73.3125
Solvent Yellow 18	21 CFR 73.3122
Carbazole violet	21 CFR 73.3107
Pigment Blue 36	21 CFR 73.3110a
Phthalocyanine green	21 CFR 73.3124

HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens contains only the amount of color additives to accomplish the intended coloring effect. The proposed color lenses are manufactured by sandwiching the pattern layer containing color additives between two layers of lens materials (polymacon). As part of the manufacturing process, the color lenses are thoroughly washed to remove the unbound reactive color additives. Because of the 'sandwich' structure, the color additives will not be removed by lens handling and cleaning procedures.

In the hydrated state, HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens conforms to the curvature of the eye covering the cornea and extending slightly beyond the limbus, and it acts as a refracting media to focus light rays on the retina. 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 compatible with the eye.

HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens is available in the spherical configuration with the following features and properties:

Back vertex power	-10.00D to 0.00D, step: 0.25D
Base curve	8.40 mm to 8.70 mm, step: 0.10 mm
Total diameter	13.80 mm to 14.50 mm, step:0.10 mm

The physical properties of the proposed lens are:

Specific gravity	1.124
Refractive index	1.437

Light Transmission	93% ± 5%
Surface character	Hydrophilic
Water content	38%
Oxygen permeability	8.99×10^{-11} (cm^2/s) [ml O_2/(ml·mmHg)] at 35℃

HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens is supplied sterile in the foil blister pack containing the borate buffer solution.

5. Intended Use/Indication for Use

HPM38 (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens is indicated for the correction of visual acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia. 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 tinted and 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.

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.

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.

6. Substantial Equivalence Comparison

Comparison item	Proposed Device (K241884)	Predicate Device (K142275)	Comment
Manufacturer	Hunan Haipuming Technology Co., Ltd.	Neo Vision Co., Ltd.	/
Product Name	HPM38 (polymacon) Daily Wear Soft (hydrophilic) Contact Lens	Neo Cosmo (polymacon) Soft (hydrophilic) Contact Lens	/
Regulation Number	21 CFR 886.5925	21 CFR 886.5925	Same
Classification	Class II	Class II	Same
Prescription Use	Yes	Yes	Same
Intended Use / Indications for Use	HPM38 (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens is indicated for the correction of visual	The Neo Cosmo (Polymacon) Soft (hydrophilic) Contact Lens is indicated for daily wear for the	Equivalent

	acuity in aphakic and not-aphakic persons with non-diseased eyes with myopia. 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 tinted and 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. 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. 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.	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 stigmatism 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.	
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.	Same
Lens Design	Spherical	Spherical, Toric	Equivalent
Manufacturing Process	Lathe-cut (semi-molded)	Lathe-cut (semi-molded)	Same
Lens Material	Polymacon	Polymacon	Same
Material Classification	Group I Low water content (<50%), Nonionic	Group I Low water content (<50%), Nonionic	Same
Color Additives	Reactive Black 5	Reactive Black 5	Different

	(21CFR 73.3121) Titanium Dioxide (21 CFR 73.3126) Iron Oxides (21CFR 73.3125) Solvent Yellow 18 (21CFR 73.3122) Carbazole Violet (21CFR 73.3107) Pigment Blue 36 (21 CFR 73.3110a) Phthalocyanine Green (21 CFR 73.3124)	(21CFR 73.3121) Titanium Dioxide (White) (21 CFR 73.3126) Iron Oxides(Red) (21CFR 73.3125) C.I Pigment Green 7 (21CFR 73.3124) (Phthalocyaninato(2-)) Copper (21CFR 74.3045)	
Storage Solution	Borate buffer solution	NaCl 0.85~0.95%(w/v) solution	Different
Primary Packaging	Blister pack	Blister pack and Vial	Equivalent
Total Diameter	13.80 mm to 14.50 mm	13.5 mm to 14.5 mm	Equivalent
Base Curve	8.40 mm to 8.70 mm	8.3 mm to 9.0 mm	
Center Thickness (varies with power)	0.050 mm to 0.090 mm	0.03 mm to 0.50 mm	Equivalent
Power Range	-10.00D to 0.00D	-25.00D to +25.00D	Equivalent
Water Content	38% ±2 %	38% ±2 %	Same
Spectral Transmission	93% ± 5%	>90%	Different
Refraction Index	1.437	1.428	
Oxygen Permeability	8.99×10^{-11} (cm^2/s) [ml O_2/(ml·mmHg)] at 35℃	9.77×10^{-11} (cm^2/s) [ml O_2/(ml·mmHg)] at 35℃	
Modulus	0.61 MPa	0.350 MPa	
Tensile Strength	0.62 MPa	0.425 MPa	
Elongation at break	279%	127%	
Sterilization	Moist Heat Sterilization	Moist Heat Sterilization	Same
Biocompatibility	Biocompatible	Biocompatible	Same

HPM38 (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens has the similar indication for use as the predicate device as well as similar technical characteristics, and the differences don't raise any additional questions for safety and effectiveness, therefore, the proposed device is substantially equivalent to the predicate device.

7. Summary of Non-clinical Testing

Non-clinical tests were conducted in accordance with the FDA guidance - *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses"* issued on June 27, 1994. The non-clinical performance tests had demonstrated the safety and effectiveness of HPM38 (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens and the substantial equivalence to the predicate device.

- **Performance Testing**

The physical, optical, physicochemical and mechanical performance tests were performed in accordance with ISO 18369-2:2017, ISO 18369-3:2017, ISO 18369-4:2017 and ASTM D882-18, and the test results showed that the proposed device meets the requirements.

- Appearance
- Physical parameters (Total diameter, Base curve, Center thickness)
- Optical parameter (Back vertex power)
- Spectral transmission
- Refractive index
- Water content
- Specific gravity
- Extractables
- Oxygen permeability
- Mechanical properties
- pH and Osmolality of the storage solution

In addition, the compatibility test of the lens with the lens care regimen has been conducted as per ISO 11981:2017, and the results demonstrate the proposed device is compatible with the marketed lens care regimens. The leachability of the color additives has also been conducted, and the results also demonstrate that the color additives contained in the proposed device are stable.

- **Biocompatibility Testing**

The following biocompatibility tests were performed respectively on the contact lens and primary packaging according to FDA guidance - *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses"* issued on June 27, 1994, and the test results demonstrated that the contact lens and primary packaging have no cytotoxicity, no ocular irritation, no skin sensitization and no acute systemic toxicity.

- Cytotoxicity (ISO 10993-5:2009)
- Ocular Irritation (ISO 10993-23:2021)
- Skin Sensitization (ISO 10993-10:2021)
- Acute System Toxicity (ISO 10993-11:2017)

In addition, the following biocompatibility tests were performed on the storage solution, and the test

results demonstrated that the storage solution had no cytotoxicity, no ocular irritation and no skin sensitization.

- Cytotoxicity (ISO 10993-5:2009)
- Ocular Irritation (ISO 10993-23:2021)
- Skin Sensitization (ISO 10993-10:2021)

In conclusion, the results of the above biocompatibility tests showed that the proposed device has no biocompatibility issues.

- **Sterilization**

A Sterility Assurance Level (SAL) of 10^{-6} has been validated in accordance with the requirements of ISO 17665-1:2006.

- **Shelf Life**

Accelerated aging testing has been performed to assure the shelf-life of 5 years in accordance with ISO 11987:2012.

- **Simulated Transportation Testing**

The simulated transportation testing has been conducted according to ASTM D4169-22.

8. Clinical Testing

This 510(k) submission does not utilize clinical study for establishing substantial equivalence therefore this section does not apply.

9. Conclusions

The results of comparing the design specifications and non-clinical testing between the proposed device and the legally marketed predicate device (K142275) show that they are Substantially Equivalent (SE).