U.S. FOOD & DRUG ADMINISTRATION

September 8, 2022

Shenzhen Dashicheng Optical Technology Co., Ltd.
℅ Grace Liu
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Shenzhen, Guangdong 518000
China

Re: K220143
Trade/Device Name: BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (Hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL, MVN
Dated: August 3, 2022
Received: August 3, 2022

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 (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 titled, "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)*
K220143

Device Name
BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens

Indications for Use *(Describe)*
BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens are 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.

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.

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510(k) Summary - K220143

1. Contact Details

1.1 Applicant information

Applicant Name	Shenzhen Dashicheng Optical Technology Co., Ltd.
Address	101, 201 and 301, Unit 3, Building 1, Wanjiening Industrial Park, No. 1450, Guanguang Road, Jutang Community, Fucheng Sub-district, Longhua District, Shenzhen, Guangdong, China
Contact person	Jiayi Li
Phone No.	+86-136 3296 6073
E-mail	lijiayi6073@dingtalk.com
Date Prepared	2022-01-11

1.2 Submission Correspondent

卓远天成	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; Field Fu;
Contact person's e-mail	grace@cefda.com; field@cefda.com
Website	http://www.cefda.com

2. Device Information`

Trade name	BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens
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	VASSEN COLOR (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Clear & Tinted)
510(k) Number	K141699
Product Code	LPL, MVN
Manufacturer	Vassen Co., Ltd.

4. Device Description

BARBIE (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 nonionic 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.

BARBIE (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
Iron oxides	21 CFR 73.3125
Solvent Yellow 18	21 CFR 73.3122
Titanium dioxide	21 CFR 73.3126
Carbazole violet	21 CFR 73.3107
Pigment Blue 36	21 CFR 73.3110a
Phthalocyanine green	21 CFR 73.3124

The proposed lenses contain 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/disinfecting procedures. The cosmetic tinting pattern has a minimum clear pupil diameter of 6.0 mm.

In the hydrated state, BARBIE (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.

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

Total diameter:	13.50 mm to 14.50 mm, step:0.10 mm
Base curve:	8.00 mm to 9.00 mm, step: 0.10 mm
Center thickness:	0.050 mm to 0.120 mm
Back vertex power:	-10.00D to 0.00D, step: 0.25D

The physical properties of the proposed lens are:

Refractive index:	1.435
Light Transmission:	≥95% (at clear region corresponding to pupil, minimum 6.0 mm diameter)
Surface character:	Hydrophilic
Water content:	38%
Oxygen permeability:	9.01×10^{-11} (cm^2/s) [ml O_2/(ml·mmHg)] at 35℃ (revised Fatt method)

BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens is supplied sterile in the foil blister pack containing standard saline solution.

5. Intended Use/Indication for Use

BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens are 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.

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.

6. Substantial Equivalence Comparison

Table 1 Substantial Equivalence Comparison

Comparison item	Proposed Device (K220143)	Predicate Device (K141699)	Comment
Manufacturer	Shenzhen Dashicheng Optical Technology Co., Ltd.	Vassen Co., Ltd.	None
Product Name	BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens	VASSEN COLOR (polymacon) Daily Wear Soft (hydrophilic) Contact Lenses (Clear & Tinted)	None
Product Code	LPL, MVN	LPL, MVN	Same
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	BARBIE (polymacon) Daily Wear Soft (Hydrophilic) Contact Lens are 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. 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.	The VASSEN COLOR (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 0.50 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	Similar

		they are to be discarded after a single use.	
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	Same
Manufacturing Process	Fully-molded	Fully-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 Iron Oxides Solvent Yellow 18 Titanium Dioxide Carbazole Violet Pigment Blue 36 Phthalocyanine Green	C.I. Reactive black 5 Iron Oxide (Red) D&C Yellow 10 Titanium Dioxide D&C Green 6 C.I. Reactive Blue 19	Different
Storage Solution	Standard saline solution	Standard saline solution	Same
Primary Packaging	Foil blister pack	Foil blister pack	Same
Total Diameter	13.50 mm to 14.50 mm	13.00 mm to 15.00 mm	Similar
Base Curve	8.00 mm to 9.00 mm	8.0 mm to 9.0 mm	Same
Center Thickness (varies with power)	0.050 mm to 0.120 mm	0.06 mm to 0.17 mm	Similar
Power Range	-10.00D to 0.00D	-10.00D to +3.00D	Similar
Water Content	38% ±2 %	38% ±2 %	Same
Light Transmission	≥95%	≥95%	Same
Refraction Index	1.435	1.439	Different
Oxygen Permeability	9.01×10^{-11} (cm^2/s) [ml O_2/(ml·mmHg)] at 35℃ (revised Fatt method)	10.55×10^{-11} (cm^2/s) [ml O_2/(ml·mmHg)] at 35℃ (revised Fatt method)	Different
Modulus	0.90 MPa	0.91 MPa	Different
Tensile Strength	0.71 MPa	0.63 MPa	
Elongation at break	110%	106%	
Toughness	0.79 N·mm	0.78 N·mm	

(Work)			
Sterilization	Moist Heat Sterilization	Moist Heat Sterilization	Same
Biocompatibility	Biocompatible	Biocompatible	Same

The proposed device has the similar indication for use as the predicate device as well as comparable technical and biocompatibility properties and 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. Non-clinical Testing

All tests were conducted in accordance with the FDA guidance - *Premarket Notification 510(k) Guidance Document for Daily Wear Contact Lenses, Revised May 1994*. The non-clinical performance tests had been performed to demonstrate the safety and effectiveness of BARBIE (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.

- Physical parameters (Total diameter, Base curve, Center thickness)
- Optical parameter (Back vertex power)
- Light transmission
- Refractive index
- Water content
- Extractables
- Oxygen permeability
- Mechanical properties

- **Biocompatibility Testing**

The following biocompatibility tests were performed respectively on the contact lens, storage solution and primary packaging, and the test results showed that the proposed device has no biocompatibility issues.

- Cytotoxicity (ISO 10993-5:2009)
- Ocular Irritation (ISO 10993-10:2010)
- Skin Sensitization (ISO 10993-10:2010)
- Acute System Toxicity (ISO 10993-11:2017)

- **Sterilization**

A Sterility Assurance Level (SAL) of 10^{-6} has been validated in accordance with the requirements of ISO 17665-1:2006 and ISO/TS 17665-2:2009.

- **Shelf Life**

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

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 (K141699) show that they are Substantially Equivalent (SE).