November 30, 2017

P L Overseas Limited
% Rain Yip
Official Correspondent
Feiying Drug & Medical Consulting Technical Service Group
Rm. 3005
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P.R. China

Re: K172925
Trade/Device Name: Contact Lens Case, Model: A-1, B-1
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: September 16, 2017
Received: September 25, 2017

Dear Rain Yip:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Denise L. Hampton -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)*
K172925

Device Name
Contact Lens Case

Indications for Use *(Describe)*
For storage of soft (hydrophilic), hard and rigid gas permeable (RGP) contact lenses during chemical disinfection. Use for storage during chemical disinfection only. Do not use during heat disinfection.

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.

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510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 16/09/2017

I. Submitter

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II. Device

Name of Device: Contact Lens Case
Common or Usual Name: Contact Lens Case
Classification Name: Case, Contact Lens
Regulatory Class: II
Product Code: LRX
Regulation Number: 21 CFR 886.5928

III. Predicate Device

1） The predicate devices are listed as below:

Manufacturer	Predicate Device	510(k) Number	Approval Date
Ningbo Yinzhou Zonghai Artware Co., Ltd	Contact Lens Case	K162869	December 9, 2016
MACA Plastics Inc	Contact Lens Case	K140488	September 10, 2014

2） No reference devices were used in this submission.

IV. Device Description

The Contact Lens Case is a lens case product to be used by the contact lens wearer or practitioner for storing soft (hydrophilic), hard and rigid gas permeable contact lenses during chemical disinfection. The Case is to be designed during chemical disinfection only. No designed for heat disinfecting system.

The Contact Lens Case includes A-1 and B-1 two models. Both have adopted the same structure design, consisting of two parts: holder and cover. The holder is based with adjoining dual wells for the containment of fluid, and two covers are designed for screwing. At the same time, the bottom of each well is marked with L (left) and R (right) letters, and the covers are also labeled with L (left) and R (right) letters.

The Contact Lens Case is simple with a well volume of 4.2mL±0.15. This volume capacity can provide sufficient space to insert and retrieve the contact lenses. It also provides sufficient space to introduce the chemical cleaning solution and adequately over the lenses for cleaning.

V. Indications for Use

For storage of soft (hydrophilic), hard and rigid gas permeable (RGP) contact lenses during chemical disinfection.
Use for storage during chemical disinfection only. Do not use during heat disinfection.

VI. Comparison of Technological Characteristics With the Predicate Device

The Contact Lens Case is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.
1) K1628690, "Contact Lens Case", manufactured by "Ningbo Yinzhou Zonghai Artware Co., Ltd" in Zhejiang, China
2) K140488, "Contact Lens Case", manufactured by "MACA Plastics Inc" in Ohio, U.S.A

The following table shows similarities and differences of use, design, material, safety and effectiveness between the subject device and predicate devices.

Comparison Table

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**
1.Classification			
Device Name	Contact Lens Case	Contact Lens Case K162869	Contact Lens Case K140488
Classification Name	Case, Contact Lens	Case, Contact Lens	Case, Contact Lens
Classification Advisory Committee	Ophthalmic	Ophthalmic	Ophthalmic
Class	II	II	II

Comparison Elements	**Subject Device**	**Predicate Device 1**	**Predicate Device 2**
Regulation Number	21CRF 886.5928	21CRF 886.5928	21CRF 886.5928
Product Code	LRX	LRX	LRX
Comparison Statement	The subject device has the same classification as the predicate devices.		
2. Intended Use			
Intended Use	For storage of soft (hydrophilic), hard and rigid gas permeable (RGP) contact lenses during chemical disinfection. Use for storage during chemical disinfection only. Do not use during heat disinfection.	For storage of soft (hydrophilic), hard and rigid gas permeable contact lenses during chemical disinfection. Use for storage during chemical disinfection only. DO NOT USE WITH HEAT.	For storage of soft (hydrophilic), hard and rigid gas permeable contact lenses during chemical disinfections. Use for storage during chemical disinfection only. Do not use heat disinfection.
Comparison Statement	The subject device has the same intended use as the predicate devices.		
3.Design/Material			
Disinfection Type	Chemical Disinfection Not heat-Disinfection	Chemical Disinfection Not heat-Disinfection	Chemical Disinfection Not heat-Disinfection
Sterilization	Not sold sterile	Not sold sterile	Not sold sterile
Design	Holder with two wells to hold fluid and two covers for the Left and Right eyes of contact lenses The covers are designed for screwing.	Shaped base with two wells to hold fluid and two screw lids for the Left and Right eyes of contact lenses	Two adjoining chambers with screw top into which contact lenses are immersed.
Dimension (L*W*H)	A-1 64*31*16mm B-1 65*31*15mm	63*32*16mm	Unknown
Volume (Each well)	4.2mL±0.15	4.8mL	Over 3.0mL
Materials	A-1 Holder: Polypropylene	BASE: Polypropylene (PP)	Polypropylene (PP) and Arcylonitrile-

Comparison Elements	**Subject Device**		**Predicate Device 1**	**Predicate Device 2**
		(PP) Cover: High-density Polyethylene (HDPE)	LID: Polyethylene (PE)	Butadiene-Styrene copolymer (ABS)
	B-1	Acrylonitrile-Butadiene-Styrene copolymer (ABS)		
Comparison Statement	The subject device has a similar product design as the predicate device. The minor difference is material and appearance, which will be discussed and demonstrated in "Safety Elements" below.			
4.Effectiveness				
Effectiveness	The capacity is sufficient for contact lens to be fully immersed under use condition.		The capacity is sufficient for contact lens to be fully immersed under use condition.	The capacity is sufficient for contact lens to be fully immersed under use condition.
Comparison Statement	The subject device has the same performance effectiveness as the predicate devices.			
5.Safety Elements				
Biocompatibility	Complying with ISO 10993-1: -Cytotoxicity (ISO10993-5) -Skin Sensitization (ISO10993-10) -Ocular Irritation (ISO10993-10) -Systematic Toxicity (ISO10993-11)		Complying with ISO10993-1: -Cytotoxicity (ISO10993-5) -Skin Sensitization (ISO10993-10) -Ocular Irritation (ISO10993-10) -Systematic Toxicity (ISO10993-11)	Unknown
Leakage Test	No Leakage		No Leakage	Unknown
Comparison Statement	The A-1 Model of the subject device is made of similar materials as the Predicate Device 1 and B-1 Model of the subject device is made of the same material as the Predicate Device 2. Meanwhile, the subject device was tested relevant biocompatibility tests in accordance with Product Guidance and ISO10993 standards as recognized by FDA; the test results met all			

Comparison Elements	Subject Device	Predicate Device 1	Predicate Device 2
	relevant requirements in test standards, and are comparable to the predicate device. The subject device has the same performance effectiveness as the predicate devices.		

VII. Performance Data

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

Non-Clinical Data:

1) Biocompatibility Testing

The biocompatibility evaluation for the Contact Lens Case was conducted in accordance with the "Use of International Standard ISO 10993-1, 'Biological Evaluation of Medical Devices –Part 1: Evaluation and Testing Within a Risk Management Process, Document Issued on June 16, 2016", as recognized by FDA. The battery of testing included the following tests:

- ISO 10993-5:2009/(R)2014, Biological Evaluation of Medical Devices –Par t 5: Tests for In Vitro Cytotoxicity
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Par t 10: Tests for Irritation and Skin Sensitization
- ISO 10993-10:2010, Biological Evaluation of Medical Devices –Par t 10: Tests for Ocular Irritation
- ISO 10993-11:2006/(R)2010, Biological Evaluation of Medical Devices –Par t 11: Tests for Systemic Toxicity

All tests were passed.

2) Leakage Testing

Leakage testing was conducted to the Contact Lens Case samples. 120 combinations of different tops and bottoms were filled to 2/3 with liquid. Each set was turned upside down for 15 minutes and the test were repeated 3 times.
None of the tested contact lens cases showed any leakage and all passed the leakage tests successfully.
The test results show the Contact Lens Case complies with the requirement as defined.

Clinical Data

Clinical studies were unnecessary for this application. Lens case solutions used with this contact lens case are already cleared for use as cleaning, rinsing, disinfection and storage solutions for soft (hydrophilic), hard and rigid gas permeable (RGP) contact lenses.

Summary

Based on the above performance as documented in this application, Contact Lens Case was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. Conclusions

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the comparison of intended use, design, materials and performance, the Contact Lens Case is to be concluded substantial equivalent to its predicate devices.