DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 14, 2017

E-Link Plastic & Metal Industrial Co.,Ltd
% Long Yang
COO
Shenzhen Hlongmed Biotech Company
1002, 10th Floor, Zhongxing Administrative Building
Zhongxing Industrial Zone, Chuangye Road, Nanshan
Shenzhen, China 518054 Guangdong

Re: K171539
Trade/Device Name: Contact Lens Case
Model: ELENS-001-001, ELENS-001-002, ELENS-001-003, ELENS-003-001
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: May 15, 2017
Received: May 26, 2017

Dear Long Yang:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -S

for Malvina 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171539

Device Name
Contact Lens Case
Model: ELENS-001-001, ELENS-001-002, ELENS-001-003, ELENS-003-001

Indications for Use *(Describe)*
The Contact Lens Case is a device intended for storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for 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 the requirements of SMDA 1990 and 21 CFR §807.92.

1. Submitter

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3. Date Prepared: May 15, 2017

4. Proposed Device Information

Trade name: Contact Lens Case

Model: ELENS-001-001, ELENS-001-002, ELENS-001-003, ELENS-003-001

Common name: Contact Lens Case

Classification name: Soft (hydrophilic) contact lens care products

Review Panel: Ophthalmic

Product Code: LRX

Regulation Class: II

Regulation Number: 21 CFR 886.5928

5. Predicate Device Information

Manufacturer	Device Name	510(K) Number
Ningbo Lishunda Electronics Co.,Ltd	"OWL Contact Lens Cases" and "DOG Contact Lens Case" (or other clients private labeling)	K130930

6. Device Description

The Contact lens case is medical device for the storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. The applicant device of Contact Lens Case consists of two parts: case body and case lids. The case body based with adjoining dual wells for the containment of fluid, and the two lids are designed for screwing.

All the four variant models of this device have a capacity of 5.3 ml to allow contact lenses fully immersed into the well, and the well from these models accommodates all lenses currently being sold in the market. In addition, the contact lens case are made of polypropylene (96%) and Polyethylene (4%), which allow the same design principle with the same intended use.

Speaking of the labeling, the inner lids of the case are marked with **L** (left) or **R** (right),

meanwhile the bottom of each well is also labeled with L (left) or R (right) to distinguish the left and right lenses. In addition, at the bottom of the case body, two sides of which have labeled **REPLACE MONTHLY** respectively to remind user to replace the contact lens case at least once every month.

7. Indications for use

The Contact Lens Case is a device intended for storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for use during heat disinfection.

8. Comparison to Predicate Device

The contact lens case has the same intended use, similar design and materials as the following predicate device and is substantially equivalent with regards to safety and effectiveness.

(1) K130930 "OWL Contact Lens Cases" and "DOG Contact Lens Case", manufactured by Ningbo Lishundo Electronics Co., Ltd

The following table shows similarities and differences of technological characteristics between our device and the predicate devices.

Item	Proposed Device	Predicate Devices
Trade Name	Contact Lens Case	"OWL Contact Lens Cases" and "DOG Contact Lens Case"
Model	ELENS-001-001, ELENS-001-002, ELENS-001-003, ELENS-003-001	- -
510(k) Submitter	E-Link Plastic & Metal Industrial Co.,Ltd.	Ningbo Lishunda Electronics Co.,Ltd
510(k) Number	Pending	K130930

Classifications Name & Citations	21 CFR 886.5928 Soft (hydrophilic) contact lens care products (LRX)	21 CFR 886.5928 Soft (hydrophilic) contact lens care products (LRX)
Intended for Use	Intended for storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for use during heat disinfection.	Intended for the storage of soft (hydrophilic), rigid gas permeable, and/or hard contact lenses. Used for storage during chemical disinfection only. Not for use during heat disinfection.
Basic Design	Two adjoining wells with screw down lids	Two adjoining wells with screw down lids
Materials	Polypropylene(96%) Polyethylene (4%)	Acrylonitrile-Butadiene-Styrene Copolymer (ABS)
Size (length × width × height)	ELENS-001 series: 64.40 × 31.95 × 19.30 mm ELENS-003-001： 66.44 × 32.94 × 28.69 mm	OWL: 71 ×38.5 ×17 mm DOG: 69.5 ×38 ×14 mm
Volume	5.3 ml	5.5ml (OWL) and 4.8 ml (DOG)
Outer Lid Colors	Two	Three
Sterility	No	No
Disinfection type	Chemical disinfection No heat-disinfection	Chemical disinfection No heat-disinfection
Cytotoxicity (ISO 10993-5)	No cytotoxicity	No cytotoxicity
Irritation (1SO 10993-10)	No irritation	No irritation
Systematic Toxicity (ISO 10993-I1)	No systematic toxicity	No systematic toxicity
Leakage Test	No leakage	No leakage

Our device and the predicate device differ in the following areas.

(1) Our device is made from polypropylene (96%) and Polyethylene (4%), while the predicate devices “OWL Contact Lens Cases” and “DOG Contact Lens Case” are made from Acrylonitrile-Butadiene-Styrene Copolymer.

This difference does not affect the effectiveness and safety of our devices. Our device has

been tested for cytotoxicity, irritation, and systemic toxicity. All results show that material is not cytotoxic, causes no irritation, and has no systemic toxicity.

(2) Other minor difference that do not affect the safety and performance of our device: the predicate device "OWL Contact Lens Cases" and "DOG Contact Lens Case" have the plain tops, while our device (model: ELENS-003-001) have an animal shaped part on the top lid as well as ELENS-001 series have the plain tops. These differences of appearance would not affect the clinical use of the device. Besides, the volume of each chamber in our device is 5.3 ml (ELENS-001 series: 64.40 × 31.95 × 19.30 mm and ELENS-003-001 : 66.44 × 32.94 × 28.69 mm), the volume of each chamber in "OWL Contact Lens Cases" and "DOG Contact Lens Case" are 5.5 ml and 4.8 ml . Although the volume of our device is different than the predicate, it is designed within the range of these acceptable volumes (4.4 ml ~5.5 ml), which any contact lens on the market can be fully immersed in the chambers due to the sizes of all contact lenses on the market are no larger than 1.4 cm diameter × 0.35 cm height.

9. Non-Clinical Performance Data

Biocompatibility Tests

The Contact Lens Case has been evaluated in accordance with Part 10993 of the International Standard Organization (ISO). Standard tests administered include:

- ISO 10993-5: 2009 Biological Evaluation of Medical Devices - Part 5: Tests for in vitro cytotoxicity. The test article is considered non-cytotoxic under the conditions of the test.
- ISO 10993-10 2010 Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin sensitization. Under the conditions of this study, the Contact Lens Cases were classified as non-irritating.
- ISO 10993-11: 2006 Biological Evaluation of Medical Devices - Part 11: Tests for Systemic Toxicity. The requirements of the ISO Acute Systemic Test have been met by the test article.

Leak Test

To prove the sealing performance of the Contact Lens Case, the device has undergone the leakage testing. The water was put inside the box, natural be locked and sloshing around 180° for 0.5 h. The result is shown that the device has passed the test successfully.

Color Fastness Test

The Contact Lens Case also has undergone the tests of color fastness to crocking (based on AATCC 116-2013) and color fastness to light (based on AATCC TM 16.3-2014), the result has indicate the good color fastness of our device to light and crocking.

10. Substantial Equivalent Conclusions

Contact Lens Case has the same intended use, similar technological characteristics as the predicate device. Moreover, non-clinical testing contained in this submission demonstrated that any difference in their technological characteristics does not raise any new issues of safety and effectiveness.

In conclusion, Contact Lens Case is substantial equivalent to the predicate device.

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