December 9, 2016

Ningbo Yinzhou Zonghai Artware Co., Ltd.
c/o Mr. Charles Mack
IRC
7808 Rush Creek Drive
Pasco, WA 99301

Re: K162869
Trade/Device Name: Contact Lens Case
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX
Dated: September 28, 2016
Received: October 13, 2016

Dear Mr. Mack:

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 yours,

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
510(k) Number (if known)
K162869

Device Name
Contact Lens Case

Indications for Use (Describe)
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.

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.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

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

Date: September 30, 2016

1. Company and Correspondent making the submission:
   Name – Ningbo Yinzhou Zonghai Artware Co., Ltd.
   Address – Honglianchi, Guangsheng Village, Jishigang Town, Yinzhou District, Ningbo City Zhejiang Province, China 315172
   Tel: +86-574-88003277
   Fax: +86-574-88003255
   Contact – Mr. Weng Changhai
   General Manager
   Email – : sales1@zonghai.net

   US Correspondent
   Name- IRC, Charles Mack
   Address- 2091 Oak Drive, Lake Havasu City, Arizona 86406
   Tel: 931-625-4938
   Principal Engineer
   Email- charliemack@irc-us.com

2. Device :
   Trade/proprietary name: Contact Lens Case
   Common Name : Contact Lens Case
   Classification Name : case, contact lens

3. Predicate Devices :

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Predicate Device</th>
<th>510(k) Number</th>
<th>Submitted Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ni Hau Industrial Co., Ltd.</td>
<td>Cat Contact Lens Case, Sunglasses Contact Lens Case</td>
<td>K142717</td>
<td>Contact Lens Case</td>
</tr>
<tr>
<td></td>
<td>1st Contact Lens Case, Geeky Eye Contact Lens Case</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

4. Classifications Names & Citations :
   21CFR 886.5928, LRX, Contact Lens Case
5. Description:
The Contact Lens Case is a simple device made with a polypropylene base and a polyethylene lid to store soft (hydrophilic), hard, and rigid gas permeable contact lenses during chemical disinfections. This device is manufactured only for chemical disinfections with approved chemical cleaning agents to clean contact lenses. The physical style is simple with a base volume of 4.8 milliliter and dimensions of 6.25 mm wide and 9.25 mm high. This provides sufficient space to insert and retrieve the contact lenses. It also provides sufficient space to introduce the chemical cleaning solution and adequately cover the lenses for cleaning.

6. Indication for use:
For storage of soft (hydrophilic), hard, and rigid gas permeable contact lenses during chemical disinfections. Use for storage during chemical disinfections only. DO NOT USE WITH HEAT

7. Testing summary:
Biocompatibility testing was conducted as noted below:

ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity. The purpose of the test is to assess the potential cytotoxicity of test article Contact Lens Case in the In Vitro Cytotoxicity Test using L929 mouse fibroblast cells (From ATCC), which was sensitive to extractable cytotoxic articles. Under the conditions of this study, the test articles Contact Lens Case extract did not show potential toxicity to L-929 cells with polar and non-polar extracts.

ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The test was designed to evaluate the potential of a test article extract to cause ocular irritation. According to what observed, the response of ocular on testing side does not exceed that on the control side. Thus, it is identified as grade 0. All animals were not found abnormal clinical symptoms except ocular reactions. All animals were normal weight change. Under the conditions of this study, the test article extracts showed no significant evidence of causing ocular irritation.

ISO 10993-10 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization. The purpose of this test is to evaluate the potential of a test article extract to cause skin sensitization in the guinea pig. All animals were not found abnormal clinical symptoms except skin reactions. All animals were normal weight change. The positive rate of all test group animals was 0%. The positive rate of all negative control animals was 0%. Under the conditions of this study, the test article extract showed no significant evidence of causing skin sensitization in the guinea pig.
ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity. The purpose of this testing was to evaluate the potential of a test article extract to cause acute systemic toxicity in mouse. No animals were found with any abnormal clinical symptoms. All animals had normal weight change. Under the conditions of this study, the test article extracts showed no significant evidence of causing acute systemic toxicity in the mice.

Leakage testing was conducted to the contact lens case samples. 240 combinations of different tops and bottoms were filled to 2/3 with liquid. Each set was turned upside down for 15 minutes and the tests 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.

8. Comparison with predicate device:
Ningbo Yinzhou Zonghai Artware Co., Ltd. believes that the Contact Lens Case is substantially equivalent to the (K142717) Ni Hau Industrial Co., Ltd. Cat Contact Lens Case; Sunglasses Contact Lens Case; 1st Contact Lens Case; Geeky Eye Contact Lens Case.
<table>
<thead>
<tr>
<th>Element of comparison</th>
<th>Subject Device</th>
<th>Predict Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Company</td>
<td>Ningbo Yinzhou Zonghai Artware Co., Ltd.</td>
<td>Ni Hau Industrial Co., Ltd.</td>
</tr>
<tr>
<td>FDA510(K) Number</td>
<td>N/A</td>
<td>K142717</td>
</tr>
<tr>
<td>Device Name</td>
<td>Contact Lens Case</td>
<td>Cat Contact Lens Case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sunglasses Contact Lens Case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1st Contact Lens Case</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Geeky Eye Contact Lens Case</td>
</tr>
<tr>
<td>Classification</td>
<td>CFR 886.5928, Class II</td>
<td>CFR 886.5928, Class II</td>
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<tr>
<td>Product Code</td>
<td>LRX</td>
<td>LRX</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>For storage of soft (hydrophilic), hard, and rigid gas permeable contact lenses during chemical disinfections. Use for storage during chemical disinfections only. DO NOT USE WITH HEAT.</td>
<td>For storage of soft (hydrophilic), hard, and rigid gas permeable contact lenses during chemical disinfection. Use for storage during chemical disinfections only. DO NOT USE WITH HEAT.</td>
</tr>
<tr>
<td>Case Dimension</td>
<td>63x32x16mm</td>
<td>Cat: 65 x 37 x 14mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sunglasses: 71 x 31 x 14mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1st Contact: 60 x 39.6 mm</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Geeky eyes: 80 x 32 x 21mm</td>
</tr>
<tr>
<td>Single Well Capacity Volume</td>
<td>4.8ml</td>
<td>Cat: 3ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sunglasses: 2.5ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1st Contact: 3ml</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Geeky eyes: 2.8ml</td>
</tr>
<tr>
<td>Device Material</td>
<td>BASE: Polypropylene(PP)</td>
<td>Acrylonitrile Butadene Styrene(ABS)</td>
</tr>
<tr>
<td></td>
<td>LID: Polyethylene(PE)</td>
<td></td>
</tr>
<tr>
<td>Device Construction</td>
<td>Shaped base with two wells to hold the fluid and two screw lids for the Left and Right eyes of contact lenses.</td>
<td>Shaped base with two wells to hold the fluid and two screw lids for the Left and Right eyes of contact lenses.</td>
</tr>
<tr>
<td>Screw On Caps</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>R/L indications on chamber bottoms and/or top</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>Complying with ISO10993-1: - Cytotoxicity (ISO 10993-5) - Skin sensitization (ISO10993-10) - Ocular Irritation (ISO 10993-10) - Systematic Toxicity (ISO10993-11)</td>
<td>PASS the following test: - Cytotoxicity (ISO 10993-5) - Eye Irritation (ISO 10993-10) - Systematic Toxicity (ISO10993-11)</td>
</tr>
<tr>
<td>Disinfection Type</td>
<td>Chemical disinfection, not heat disinfection.</td>
<td>Chemical disinfection, not heat disinfection.</td>
</tr>
<tr>
<td>Sterilization</td>
<td>Not sold sterile</td>
<td>Not sold sterile</td>
</tr>
</tbody>
</table>
9. Safety and Performance Data:

<table>
<thead>
<tr>
<th>Serial Number/Version</th>
<th>Standard and Description</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>ISO10993-10:</td>
<td>Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization</td>
<td>Biocompatibility Testing</td>
</tr>
<tr>
<td>ISO10993-10:</td>
<td>Biological evaluation of medical devices - Part 10: Tests for ocular irritation</td>
<td>Biocompatibility Testing</td>
</tr>
</tbody>
</table>

10. Clinical: No clinical tests were performed.

11. The basic design of the submitted device specifications is substantially the same as the predicate, with differences in the aesthetic design and plastic material. Though the plastic material is different, biocompatibility testing has verified that the submitted device is safe for use.

All the labeling and characteristics of the submitted OTC Contact Lens Case is the same as the predicate devices and most typical OTC contact lens cases currently on the market. The submitted device and predicate both are used for storage and disinfection by chemical solution of soft (hydrophilic), hard, and rigid gas permeable contact lenses.

11. Conclusions:
   In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Ningbo Yinzhou Zonghai Artware Co., Ltd. concludes that the Contact Lens Case is substantially equivalent to predicate devices as described herein.

END