



Food and Drug Administration
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June 7, 2016

Danyang Chanxin Glasses Cases Factory
c/o Mr. Mike Gu
Regulatory Affairs Manager
OSMUNDA Medical Device Consulting Co., Ltd
Level 7, Jin Gui Business Center
982 Cunyun Road, Baiyun District, Guangzhou
Guangdong, China 510420

Re: K160005

Trade/Device Name: Contact Lens Case (multiple brand names)
Regulation Number: 21 CFR 886.5928
Regulation Name: Contact Lens Case
Regulatory Class: Class II
Product Code: LRX
Dated: April 25, 2016
Received: April 28, 2016

Dear Mr. Gu:

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" (21CFR 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

Indications for Use

510(k) Number (if known)

K160005

Device Name

Contact Lens Case

Indications for Use (Describe)

Contact Lens Case is a lens care product to be used by the contact lens wearer or practitioner for storing soft (hydrophilic) contact lenses while not being worn. Not designed for heat disinfecting system. Use only with chemical 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.

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510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

I. SUBMITTER

DANYANG CHANXIN GLASSES CASES FACTORY

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Preparing date: 30 Dec 2015

II. DEVICE

Name of Device: Contact Lens Case
Common/Usual Name: Contact Lens Case
Classification Names: Case, Contact Lens
Regulation Class: II
Product Code: LRX

III. PREDICATE DEVICE

Contact Lens Case(K071081)

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

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

Contact Lens Case is a lens care product to be used by the contact lens wearer or practitioner for storing soft(hydrophilic) contact lenses while not being worn. This device is not sterile and not for heat-disinfection. Use only with chemical disinfection.

There are two main series. One series includes the variant model DC-2001, DC-3001 and DC-6001, the other includes DC-7001 and DC-8001. All these five variant models are made of Polypropylene, which follow the same design principle with the same intended use.

All the five variant models of this device have a capacity of over 1.5 ml in each case well. And the inner height of the all wells exceeds 8.5 mm. With regard to the Center Thickness of the normal hydrophilic and hydrophobic contact lens will not outnumber 8.5 mm, the capacity is sufficient for contact lens to be fully immersed under use condition.

V. INDICATION FOR USE

Contact Lens Case is a lens care product to be used by the contact lens wearer or practitioner for storing soft(hydrophilic) contact lenses while not being worn. Not designed for heat disinfecting system. Use only with chemical disinfection.

VI. SUBSTANTIAL EQUIVALENCES

Technology: The proposed device Contact lens case has similar product design as the predicate device. The major differences are due to the different design for adjoining wells with integral hinged caps or screw-top caps, the different dimension and appearance, made of the PP material with different color additives. These are not relating to the safety or effectiveness aspects. Thus they are substantially equivalent.

Summary of Non-Clinical Leakage Testing: Production units of Contact Lens Cases have

Tests: undergone leakage testing. None of the tested lens cases showed any leakage and all of the Leakage Tests were passed successfully.

Summary of Clinical Tests: The subject of this premarket submission, Contact lens case did not require clinical studies to support substantial equivalence.

The following comparison table identifies the similarities and differences of the proposed device Contact Lens Case to the legally marketed predicate device Contact Lens Case (k071081) to which substantial equivalency is claimed.

Comparison Table of Predicate device and Proposed Device

Items	Predicate Device CONTACT LENS CASE K071081	Proposed Device CONTACT LENS CASE	Discussion of Differences
<i>Manufacturer</i>	Ningbo Kaida Rubber & Plastic Technology Co.,Ltd.	DANYANG CHANXIN GLASSES CASES FACTORY	---
<i>Device name</i>	Multiple Brand Names	Contact Lens Case	---
<i>Classification Name</i>	Contact Lens Case	Contact Lens Case	Identical
<i>Product Code</i>	LRX	LRX	Identical
<i>Intended Use</i>	The contact lens case is a lens care product to be used by the contact lens wearer or practitioner for storing contact lenses while not being worn. The device is not designed for heat disinfecting system. Use only with chemical disinfection.	Contact Lens Case is a lens care product to be used by the contact lens wearer or practitioner for storing soft(hydrophilic) contact lenses while not being worn. Not designed for heat disinfecting system. Use only with chemical disinfection.	<i>Equivalent</i>
<i>Indications for Use</i>	Storage and Disinfection of Soft, Rigid Gas permeable or Hard contact lenses while not being worn	Storage and Disinfection of Soft contact lenses while not being worn	<i>Equivalent</i>
<i>Disinfection Type</i>	Chemical Disinfection Not Heat-Disinfection	Chemical Disinfection Not Heat-Disinfection	Identical

Items	Predicate Device CONTACT LENS CASE K071081	Proposed Device CONTACT LENS CASE	Discussion of Differences
<i>Design</i>	Two adjoining Wells with Screw-Top Caps	Two adjoining Wells with Screw-Top Caps: DC-2001, DC-3001 and DC-6001 Two adjoining Wells with Integral-Hinged Caps: DC-7001 and DC-8001	<i>Equivalent</i>
<i>Main Materials</i>	Polypropylene(PP)	Polypropylene(PP)	<i>Equivalent</i>
<i>Dimension</i>	Each case well has a capacity of over 1.5 ml. The inner height of the wells exceeds 8.5mm.	Each case well has a capacity of over 1.5 ml. The inner height of the wells exceeds 8.5mm.	<i>Equivalent</i>
<i>Color</i>	Purple	colorless, transparent blue, transparent violet, blue, violet, and white	Different, the colors of proposed device have been demonstrated to be biocompatible safe.
<i>Effectiveness</i>	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.	Identical
<i>Safety</i>	ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity; ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic Toxicity.	ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity; ISO 10993-10 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization ISO 10993-11 Biological evaluation of medical devices -- Part 11: Tests for systemic Toxicity.	Identical
<i>Sterility</i>	No	No	Identical

VII. CONCLUSION

DANYANG CHANXIN GLASSES CASES FACTORY considers the Contact lens case to be as safe, as effective, and performance is substantially equivalent to the predicate device.