October 09, 2024

Shanghai Care Us Medical Product Co., Ltd.
Charles Shen
Director
Manton Business and Technology Services
37 Winding Ridge
Oakland, NJ 07436

Re: K240095
Trade/Device Name: CAREUS 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 03, 2024
Received: September 03, 2024

Dear Charles Shen:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K240095

Device Name
CAREUS Contact Lens Case

Indications for Use *(Describe)*
"CAREUS Contact Lens Case" is a device 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.

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.

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510(k) Summary: K240095

This summary of 510k safety and effectiveness information is being submitted
In accordance with the requirements of 21CFR 807.92

1 Submitter & Foreign Manufacture Identification

Shanghai Care Us Medical Product Co., Ltd.
No.2, Lane 10, West Chenchuan Road
Baoshan District Shanghai CN-31 Shanghai 200949 China
Tel：86- 15026598135
Submitter's FDA Registration Number：N/A

2 US Agent and Contact Person

Charles Shen
Manton Business and Technology Services
37 Winding Ridge, Oakland, NJ 07436
Tel: 608-217-9358
Email: cyshen@aol.com

3 Date of Summary: October 9, 2024

4 Device Name:

Proprietary Name:	"CAREUS Contact Lens Case"
Common Name:	Contact Lens Case
Classification Name:	Soft (Hydrophilic) Contact Lens Care Products
Device Classification:	2
Regulation Number:	21 CFR 886.5928
Panel: General	Ophthalmic
Product Code:	LRX

5 Predicate Device Information:

K120904, "The Polaris Dial-a-Date Contact Lens Case", manufactured by "Reliance Design & Manufacture Corp." in Tainan, Taiwan

6 Device description:

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

"CAREUS Contact Lens Cases" have six different models, differ in dimension, case color, and packaging.

The exterior of the cases total have 9 colors: white, pink, yellow, green, light green, red, purple, blue, and transparent (no color).

Contact lenses can be fully immersed into the well, and the well from both models accommodates all lenses currently being sold in the market. The bottom of each well is marked with L (left) or R (right).

CAREUS Contact Lens Cases are made of polypropylene.

7 Indications for Use:

"CAREUS Contact Lens Case" is a device 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.

8 Technological Comparison with Predicate Device

"CAREUS Contact Lens Case" is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K120904, "The Polaris Dial-a-Date Contact Lens Case", manufactured by *"*Reliance Design & Manufacture Corp.*"* in Tainan, Taiwan

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

Table 5.1: Comparison of Intended Use, Design, and Material

Description	Our Device	Predicate Device (K120904)	SE Comparison
Indication for Use	"CAREUS Contact Lens Case" is a device 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.	The Polaris Dial-a-Date Contact Lens Case is 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.	SE
Basic Design	Two adjoining wells with screw down lids	Two adjoining wells with screw down lids	SE
Materials	Polypropylene	Polypropylene	SE
Size	Various	68 x 32 x 21.5 mm (length x width x height)	Similar

Volume	3.8-4,5 mL	4.4 mL	Similar
Colors	Nine different colors	Four different colors	Similar

Our devices are the same with the predicate device in indications for use and basic design, similar to predicate devices in geometry and dimension. Our devices and the predicate device have some minor differences in dimension and color, which do not affect the safety and performance of the devices.

9 Summary of Non-Clinical Testing:

Bench testing was performed per internal procedures to ensure that the "CAREUS Contact Lens Case" met its physical and chemical specifications. All tests were verified to meet acceptance criteria.

Biocompatibility testing was performed following current version of ISO 10993-5 and ISO 10993-10:

Cytotoxicity (ISO 10993-5)
Irritation & Sensitization (ISO 10993-10)
Systematic Toxicity (ISO 10993-11)

10 Summary of Clinical Study:

Clinical Study is not performed for this device.

11 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that "CAREUS Contact Lens Case" and its predicate devices have similar indications for use, similar composition, and biocompatibility, similar manufacturing process, and similar performance.

The difference between the "CAREUS Contact Lens Case" and their predicate device do not raise any question regarding its equivalence.

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, the subject device is respectively substantially equivalent to the predicate device.