February 10, 2026

Fourth Axis LLC
Srinagesh Koushik
Managing Partner
BDRA Consulting LLC
1 Clearewater Court
Damascus, MD 20872

Re: K252175
Trade/Device Name: LANDR 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: January 12, 2026
Received: January 12, 2026

Dear Srinagesh Koushik:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252175

Please provide the device trade name(s).

LANDR Contact LENS Case

Please provide your Indications for Use below.

The LANDR Contact Lens Case is designed for storing soft (hydrophilic), rigid gas-permeable, and/or rigid contact lenses. It is only for use during storage with chemical disinfection and should not be used during heat disinfection.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510k Summary

K252175

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

Manufacturer:	Fourth Axis LLC For Fourth Axis LLC By: InnoSeek Limited Building 4, No. 3 Fuxing Fourth Street, Shunyi District, Beijing, 101300, P.R.China
Submission Correspondent:	Srinagesh Koushik, Ph.D., RAC.
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Date of Submission:	2 February, 2025
Device Information:	
Proprietary Name:	LANDR Contact Lens Case
Device Classification Name:	Contact Lens Case
Device Classification:	Class II
Regulation Number:	21 CFR 886.5928
Product Code	LRX
Classification Panel:	Ophthalmic
Predicate Device:	
Proprietary Name:	CAREUS Contact Lens Case
Device Classification Name:	Contact Lens Case
Device Classification:	Class II
Regulation Number:	21 CFR 886.5928
Product Code	LRX
Classification Panel:	Ophthalmic

Intended Use:

The LANDR Contact Lens Case is designed for storing soft (hydrophilic), rigid gas-permeable, and/or rigid contact lenses. It is only for use during storage with chemical disinfection and should not be used during heat disinfection.

Indications:

The LANDR Contact Lens Case is designed for storing soft (hydrophilic), rigid gas-permeable, and/or rigid contact lenses. It is only for use during storage with chemical disinfection and should not be used during heat disinfection.

Device Description:

The LANDR Lens Case has dual-sided storage compartments (one per lens) stacked together (Figure 1). The case uses a ball plunger to hold the detachable cases together in one piece during shipping. Each compartment is colored to differentiate the cases.

Figure 1. Pictures of the LANDR Contact Lens Case as shipped

The individual cases should be separated by pulling them apart and placing them on a flat surface right side up before use (Figure 2). When disinfecting and storing contact lenses, each case must be kept upright on a flat surface in the correct orientation (Figure 2) with the lids securely closed.

Figure 2: Correct orientation to store the lenses in multipurpose solution

Figure 3: Shows contact lenses in universal storage solution on a flat surface

Substantial Equivalence:

The following table shows the similarities and differences between the predicate and subject devices.

Description	LANDR (K252175)	CAREUS (K240095)	SE Comparision
Intended Use	The LANDR Contact Lens Case is designed for storing soft (hydrophilic), gas-permeable, and/or rigid contact lenses. It is only for use during storage with chemical disinfection and should not be used during heat disinfection.	"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.	SE
Design	Two wells with screw down lids, that can be connected for carrying ease	Two adjoining wells with screw down lids	SE
Material	Polypropylene	Polypropylene	SE
Size	Single	Various	SE
Volume	3.85 ml max fill	3.8-4.5ml	SE
Colors	Two colors in every device. Each well is a different color coded for easy identification. The device is sold in a single color combination	Nine different colors	

Description	LANDR (K252175)	CAREUS (K240095)	SE Comparision
Biocompatibility	Cytotoxicity (ISO 10993-5) Irritation & Sensitivity (ISO 10993-10) Systemic Toxicity (ISO 10993-11)	Same	SE
Performance Testing	The lens case passed simulated leak tests for 8 hours storage, including evalauting leaks when cases where stored upside down. Lens cases passed leak tests.		SE

The devices have a similar intended use, and both are manufactured using polypropylene. Both devices are intended to be used upright on a flat surface while storing contact lenses. While there are some differences in basic design and colors, they do not affect the safety and performance of the device.

Biocompatibility and Performance Tests:

The lens case passed simulated leak tests for 8 hours of storage, including evaluating leaks when cases were stored upside down. Lens cases passed leak tests.

The LANDR case was tested according to the requirements outlined in the FDA guidance document, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process." Additionally, the special controls document, Guidance Document for Contact Lens Care Products," specifies that the toxicology data from the following tests on both the plastic and gasket materials should be provided:

1. Systemic Toxicity Test
2. Acute Ocular Irritation Test

3. In-Vitro Cytotoxicity Test

The components used to manufacture LANDR cases are commonly utilized in the production of medical devices. For more information, please refer to the Biocompatibility section of this submission.

The summary of biocompatibility testing results is provided in the table below.

Test Conducted	Results	Conclusion
Acute Systemic Injection Test. ISO 10993-11 Compliant	No significant difference in biological reactivity between groups and their corresponding controls.	LANDR did not demonstrate Acute Systemic toxicity based on results of the Acute Systemic Injection Test.
Elution Cytotoxicity Test (In Vitro). ISO 10993-5 Compliant.	The test article did not exhibit reactivity (grade 0) as evidenced by the presence of normal, healthy confluent cells.	LANDR Case did not induce cytotoxicity (grade 0).
Occular Irritation Test. ISO 10993-23 compliant.	The test article did not exhibit reactivity.	LANDR case is not considered an eye irritant in the Ocular irritation test.

Conclusion:

The LANDR Case meets the biocompatibility and labeling requirements outlined in Section G. Contact Lens Cases of the Guidance for Industry—Premarket Notification (510(k) Guidance Document for Contact Lens Care Products).

In accordance with 21 CFR Part 801 and based on the information provided in support of this 510(k), Fourt Axis LLC believes the LANDR Contact Lens Case is substantially equivalent to the predicate.