August 1, 2025

Avizor S.A.
Maria Salvador
Regulatory Affairs Manager
Avenida de la Innovación, 2, Parque Leganés Tecnológico
Leganes, Madrid 28919
Spain

Re: K250495
Trade/Device Name: MINI Vp1 (pl67_f, pl61_f)
Regulation Number: 21 CFR 886.5928
Regulation Name: Soft (Hydrophilic) Contact Lens Care Products
Regulatory Class: Class II
Product Code: LRX, LPN
Dated: June 27, 2025
Received: June 27, 2025

Dear Maria Salvador:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K250495

Device Name
MINI Vp1 (pl67_f, pl61_f)

Indications for Use *(Describe)*
Is indicated for storage of soft (hydrophilic), rigid gas permeable and hard contact lenses during 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.

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: K250495

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 and Contact Details

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Submitter´s FDA Registration Number: 3012603529
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Maria Salvador
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2. Device Name:

Device Trade Name: MINI VP1 (pl67 _f, pl61_f)
Common Name: Soft (hydrophilic) contact lens care products
Classification Name: Case, Contact Lens
Device Classification: 2
Regulation Number: 886.5928
Panel: Ophthalmic
Product Code: LRX, LPN

3. Legally Marketed Predicate Device:

K240095, “CAREUS Contact Lens Case”, manufactured by Shanghai Care Us Medical Product Co., Ltd.

4. Device Description:

MINI VPl is a medical device for the storage of soft (hydrophilic) and rigid gas permeable contact lenses, during chemical disinfection. It is not to be used with heat disinfection.

This device is composed of three components: one base with two wells and two caps (a white one for the right eye lens and a grey-colored one for the left eye lens). The volume of the each well is 2.5 ml. Materials are detailed as follows:

Base white: Polypropylene
IOAP Cromofix Blanco 7-00111
Cap grey: High Density Polyethylene
Gris Bathelene PE-1766
Cap white: High Density Polyethylene
IOAP Cromofix Blanco 7-00111

MINI VPl includes two models of left eye cap, which vary only in the inscription they contain, being "L" for PL61_F and "AVIZOR" for PL67 _F. The mold and materials of both left eye caps are identical.

5. Indications for Use:

MINI VPl is indicated for storage of soft (hydrophilic), rigid gas permeable and hard contact lenses during chemical disinfection.

6. Technological Comparison with Predicate Device

MINI VP1 is compared with the following Predicate Devices in terms of intended use, design, material, specifications, and performance.

(1) K240095, "CAREUS Contact Lens Case", manufactured by Shanghai Care Us Medical Product Co., Ltd.

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

Table 1: Comparison of Intended Use, Design, and Material

Description	Predicate device (K240095)	Applicant Device (K250495)	SE Comparison
Intended use/Indications for use	CAREUS 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.	MINI VP1 (pl67_f, pl61_f) is indicated for storage of soft (hydrophilic), rigid gas permeable and hard contact lenses during chemical disinfection.	SE
Classification	Ophthalmic	Ophthalmic	SE
	886.5928 – Soft (hydrophilic) contact lens care products	886.5928 – Soft (hydrophilic) contact lens care products	SE
Product Code	LRX (Class 2) – Case, Contact Lens	LRX (Class 2) – Case, Contact Lens	SE
Materials and design	Polypropylene. One base with two wells and two caps. Several colors.Volume of 3.8-4.5 ml.	Polyethylene and Polypropylene. One base with two wells and two caps. Two colors.The volume of each well is 2.5 ml.	Similar

The applicant device has the same classification and product code as the predicate device. The applicant device has the same intended use as the predicate device. The applicant device has a similar design and is made of similar materials to the predicate device.

7. Summary of Non-Clinical Testing:

Bench testing was performed per internal procedures to ensure that the MINI VP1 lens case met its physical and chemical specifications. Also performance testing, as leak tests per internal procedure, were conducted. All tests were verified to meet acceptance criteria.

Biocompatibility testing was performed following the current versions of below standards:
Cytotoxicity per ISO 10993-5
Acute systemic injection per ISO 10993-11
Acute ocular irritation testing per ISO 10993-23

The tests concluded the following:
Based on the results obtained under laboratory testing conditions, the extract of test item, Contact Lens Case was found to be "non-cytotoxic" to the subconfluent monolayer of L-929 mouse fibroblast cells.

Based on the results of the experiment, it is concluded that the polar and non-polar extracts of test item, Contact Lens Case when administered to Swiss Albino Mice through intravenous and intraperitoneal routes respectively at a dose volume of 50 ml/kg body weight did not reveal any systemic toxicity under the experimental conditions employed. Under the experimental conditions employed and based on the observed results of the experiment, it is concluded that the polar and non-polar extract of test item, Contact Lens Case did not produce any irritant effects to the eyes of New Zealand White Rabbits as per ISO 10993 "Biological Evaluation of Medical Devices" Part 23:2021 (E) "Test for Irritation".

All testing demonstrates substantial equivalence.

8. Summary of Clinical Study:

Clinical Study is not performed for this device.

9. Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that MINI VP1 lens case and its predicate device have similar indications for use, similar composition, and biocompatibility, similar manufacturing process, and similar performance.

The difference between the MINI VP1 and its 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.