



May 2, 2022

AL.CHI.MI.A. S.r.l
% Elena Morozova
US Agent
Oftal-One Inc.
250 Catalonia Ave. Suite 606
Miami, Florida 33134

Re: DEN200063
Trade/Device Name: Kerasave
Regulation Number: 21 CFR 886.4320
Regulation Name: Corneal storage medium with preservatives including antifungals
Regulatory Class: Class II
Product Code: QCW
Dated: September 29, 2020
Received: November 10, 2020

Dear Elena Morozova:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the Kerasave, a prescription device under 21 CFR Part 801.109 with the following indications for use:

Kerasave is indicated for storage of human corneas at 2-8 C for up to 14 days. It is intended for prescription (Rx) use by physicians or highly skilled personnel, such as Eye Bank operators.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the Kerasave, and substantially equivalent devices of this generic type, into Class II under the generic name corneal storage medium with preservatives including antifungals.

FDA identifies this generic type of device as:

Corneal storage medium with preservatives including antifungals. Corneal storage medium with preservatives including antifungals is a device that is used to temporarily preserve human cornea tissue between harvesting and implantation.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two

options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On October 1, 2020, FDA received your De Novo requesting classification of the Kerasave. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Kerasave into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, the Kerasave can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Infection	Sterilization validation Non-clinical performance testing Labeling Shelf life testing
Adverse tissue reaction	Biocompatibility evaluation Non-clinical performance testing
Antimicrobial resistance	Antimicrobial resistance analysis Non-clinical performance testing Labeling
Worsening prognosis that may need recurring or more invasive surgery due to damage to cornea tissue while in storage	Non-clinical performance testing Labeling

In combination with the general controls of the FD&C Act, the corneal storage medium with preservatives including antifungals is subject to the following special controls:

- (1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use.
 - (i) The following performance characteristics of the cornea following storage in the device must be demonstrated:
 - (A) Endothelial cell density;
 - (B) Endothelial cell morphology;

- (C) Corneal transparency; and
 - (D) Central corneal thickness.
- (ii) Antimicrobial activity of the device must be demonstrated at the initial and maximum labeled storage time.
 - (iii) Characterization of all preservatives, including antifungals, must include the following:
 - (A) Characterization of impurities, heavy metal analysis, concentration, and dissolution; and
 - (B) Chemical activity of all preservatives over the labeled use life of the device
- (2) Performance data must demonstrate the sterility of the device.
 - (3) The device must be demonstrated to be biocompatible and non-pyrogenic.
 - (4) Performance data must support the claimed shelf life by demonstrating continued sterility, controlled bioburden, package integrity, and device functionality over the intended shelf life.
 - (5) The device and each of its components (e.g., antifungal, antibiotic, medium) must be demonstrated to be compatible with their respective commercial container closure system/packaging.
 - (6) An analysis must be provided that identifies and evaluates any contribution to the development and spread of antimicrobial resistance.
 - (7) Labeling must include the following instructions:
 - (i) Rinsing of cornea prior to transplantation; and
 - (ii) Complete dissolution of all preservatives.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the corneal storage medium with preservatives including antifungals they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes

and regulations administered by other Federal agencies. You must comply with all the FD&C 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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Keith Christopher at 240-402-6579.

Sincerely,

for Malvina Eydelman, M.D.

Director

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices

Office of Product Evaluation and Quality
Center for Devices and Radiological Health