October 5, 2022

Aurolab
% Sean Griffin
President
Allied Regulatory Consulting
1540 Keller Parkway, Suite 108 #170
Keller, Texas 76248

Re: K221759
Trade/Device Name: Cornisol
Regulatory Class: Unclassified
Product Code: LYX
Dated: July 6, 2022
Received: July 11, 2022

Dear Sean Griffin:

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. 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 located 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.

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) 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 Act); 21 CFR 1000-1050.

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

Anjana Jain, PhD
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
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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)*
K221759

Device Name
Cornisol

Indications for Use *(Describe)*
Cornisol is a corneal storage solution for storage of human cornea suitable for keratoplasty for up to 14 days under refrigeration (2-8°C)

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

This 510(k) summary has been prepared in accordance with 21 CFR 807.92.

Submitter

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Date Prepared: September 30, 2022

Device

Device Subject to this 510(k):

Trade Name:	Cornisol
Common Name:	Hypothermic corneal storage media
Product Code:	LYX (Media, Corneal Storage)
Classification:	Unclassified

Predicate Device

510(k) Number	Device
K924165	Optisol-GS Corneal Storage Media (Product Code: LYX - Media, Corneal Storage; Regulation: Unclassified)

Device Description

Cornisol is a sterile hypothermic corneal storage medium intended for human corneal storage between 2 and 8°C for up to 14 days. Cornisol is for single use and to be used only by physicians or highly skilled personnel such as eye bank operators. Corneas are directly placed in Cornisol medium after surgery with a storage time based on the time needed to obtain serology results of the donor but for a period of time of no more than 14 days.

Cold storage of cornea is traditionally performed by keeping corneas in a cold storage medium containing deswelling agent(s) between 2°C and 8°C.

Indications for Use

CORNISOL is a corneal storage solution for storage of human cornea suitable for keratoplasty for up to 14 days under refrigeration (2-8°C).

Physical and Performance Characteristics

CORNISOL is a sterile, buffered corneal preservation medium comprised of the ingredients shown in Table 1. It is supplied ready to use with a volume of 20 mL in a 20 mL type 1 glass vial with a polyethylene cap and PVC shrink wrap.

Table 1: Cornisol ingredients and their function

Ingredient	Function
Chondroitin Sulphate	Osmotic agent/membrane stabilizer
Dextran 40	Osmotic agent
HEPES Buffer	To maintain pH
Sodium Pyruvate	Energy source for endothelial cell viability
Gentamycin	Antibiotic
Streptomycin	Antibiotic
Sodium Bicarbonate	pH adjustment
Medium 199	Nutrient and electrolyte
Minimum Essential Medium	Nutrient and electrolyte
Glutamax i200	Energy production and helps prevent degradation
Vitamin B12	Cofactor for enzymatic reactions and membrane stabilizing agent
Phenol Red Indicator	pH indicator
Recombinant Human Insulin	Cell metabolism enhancer
Purified Water IP	Vehicle

Comparison of Technological Characteristics with the Predicate Device

Cornisol has similar technological characteristics as the predicate device (Table 2). Cornisol and the predicate device use Dextran as a deswelling agent. Cornisol and its predicate are provided sterile, are intended for single use and are provided in glass vials.

Table 2: Comparison between Cornisol and Predicate Device

Features and Characteristics	Proposed Device Cornisol	Predicate Optisol-GS (K924165)	Comparison of Proposed Device and Predicate Features
Intended Use	Hypothermic corneal storage	Hypothermic corneal storage	Same
Indications for use	CORNISOL is a corneal storage solution for storage of human cornea suitable for keratoplasty for up to 14 days under refrigeration (2-8°C).	OPTISOL is a biocompatible, enhanced tissue culture media for storage of human corneas suitable for keratoplasty for up to 14 days under refrigeration (2 - 8°C).	Same
Description	Sterile solution	Sterile solution	Both are sterile solutions
Target Population	Cornea for keratoplasty	Cornea for keratoplasty	Same
Where used	Eye bank, hospital	Eye bank, hospital	Same
Energy used	Refrigeration at 2 to 8°C	Refrigeration at 2 to 8°C	Same
Design	Single use glass vials	Single use glass vials	Similar design (single use vials)
Packaging/ How Supplied	Glass vial with screw cap top	Glass vial with screw cap top	Similar packaging (glass vial with screw top cap)
Key Ingredients	Dextran and chondroitin sulfate as osmotic agents and gentamycin and streptomycin as antibiotics	Dextran and chondroitin sulfate as osmotic agents and gentamycin and streptomycin as antibiotics	Both contain dextran and chondroitin sulfate as osmotic agents and gentamycin and streptomycin as antibiotics
Sterility	Sterile	Sterile	Both are provided sterile
Performance	Demonstrated to be equivalent to predicate device at storing corneas for up to 14 days when stored at 2 to 8°C	510(k) cleared for the storage of corneas for up to 14 days when stored at 2 to 8°C	Substantially equivalent to predicate device

Performance Data

Cornisol has undergone various testing including physicochemical testing, microbiological testing, sterilization validation, stability (shelf-life), packaging integrity testing as well as biocompatibility and in vitro testing.

Chemical characterization to assess the biocompatibility profile of the corneal storage media and primary packaging was conducted. The selected ingredients are commonly used in corneal storage media and no novel ingredients were selected. Cornisol is a buffered corneal preservation medium that includes additives like buffering agents, osmotic agents and pH adjusters/indicators, and there are no residues and process contaminants present in the solution. In addition, Cornisol does not contain polymers, ceramics and metals in the formulation that would produce degradation products of this nature.

Cornisol is a solution that is manufactured and sterilized by sterile filtration using 0.2 micron polyether sulphone membrane filters. The filters have been validated for aqueous extracts to exhibit < 0.25 EU/ml as established by Limulus Amebocyte Lysate (LAL) testing per USP<85>. A finished product endotoxin specification for Cornisol of 5 EU/device has been established and batch results confirm that Cornisol conforms with this specification.

Although Cornisol solution is sterilized by sterile filtration, the vial caps are sterilized by ethylene oxide (EO). The average daily exposure of EO to a patient shall not exceed 1.25 µg/device for EO and 5 µg/device for ECH (4 times EO limit), in compliance with the limits for IOLs in the ANSI/AAMI/ISO 10993-7:2008(R)2012 (Table C.1 in Annex C) standard. The shelf life for Cornisol is 12 months when stored at 2°C to 8°C.

Package integrity testing is performed on every batch of packaging components (vial and caps) for Cornisol by dye ingress/egress vacuum testing to ensure that the components can maintain the sterile barrier. In addition, each batch of Cornisol finished product is also tested using inverted vacuum challenge testing. Representative samples of packaging components have been tested and these results confirm ability to maintain the sterile barrier.

In addition, biocompatibility testing of Cornisol has been conducted.

- Cytotoxicity in accordance with ISO 10993-5

- Sensitization in accordance with ISO 10993-10
- Acute ocular irritation testing in accordance with ISO 10993-10

The Cornisol formulation was tested in two in vitro studies. The first was a prospective, in vitro, randomized study using paired donor corneas was performed. The assessments to determine equivalent performance were endothelial cell loss, endothelial cell density (ECD), coefficient of variance, and percentage hexagonality on days 3, 7, 10, and 14. The results indicated that Cornisol adequately preserved the cornea for up to 14 days in storage. The second study was on donor corneas to compare the structural and functional integrity of the donor corneas following storage in Cornisol or Optisol-GS. Corneas were immunostained for markers of structural integrity (ZO-1, Phalloidin) and functionality (Na+/K+ ATPase). The results indicated that Cornisol had similar performance in preserving cell structural integrity and functionality.

Conclusion

Cornisol is substantially equivalent to the predicate device, Optisol-GS. There are not different questions of safety and effectiveness with respect to the intended use and technologically characteristics between Cornisol and the predicate device.