



September 11, 2025

AL.CHI.MI.A. S.r.l
% Sean Griffin
President, Allied Regulatory Consulting
Allied Regulatory Consulting
1540 Keller Parkway, Suite 108 #170
Keller, Texas 76248

Re: K251320
Trade/Device Name: XTRA4
Regulatory Class: Unclassified
Product Code: LYX
Dated: August 7, 2025
Received: August 7, 2025

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 (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,


CLAUDINE H. KRAWCZYK -S

Claudine Krawczyk

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

510(k) Number (if known)

K251320

Device Name

XTRA4

Indications for Use (Describe)

XTRA4 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary K251320

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

Applicant

The name and address of the Applicant is:

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Application Correspondent:

Sean Griffin
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Allied Regulatory Consulting
1540 Keller Parkway, Suite 108 #170
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Phone: (817) 994-4306

Date Prepared: August 28, 2025

Device

Device Subject to this 510(k):

Device Trade Name: XTRA4
Regulatory Class: Unclassified
Product Code: LYX (Media, Corneal Storage)

Predicate Device

Device Trade Name: Optisol-GS
510(k) Number: K924165
Regulatory Class: Unclassified
Product Code: LYX (Media, Corneal Storage)

Reference Device

Device Trade Name: Cornisol
510(k) Number: K221759
Regulatory Class: Unclassified
Product Code: LYX (Media, Corneal Storage)

Device Description

XTRA4 (ref. EXT4 001-01) is a sterile hypothermic corneal storage medium intended for human corneal storage between 2 and 8°C for up to 14 days. It is designed as a single use 20 mL solution in glass vials. XTRA4 is intended to be used only by physicians or highly skilled personnel such as eye bank operators. The preservation of donor cornea is traditionally performed by storing them at temperatures between 2°C and 8°C in a storage medium containing deswelling agent(s).

Indications for Use

XTRA4 is a corneal storage solution for storage of human cornea suitable for keratoplasty for up to 14 days under refrigeration (2-8°C).

Technological Characteristics

XTRA4 is a sterile, buffered corneal preservation medium containing the ingredients shown in Table 1. It is supplied ready to use with a volume of 20 mL in a 20 mL borosilicate type I glass vial with a high-density polyethylene (HDPE) (outer) / Polypropylene (PP) (inner) Clic-Loc® closure cap with Polyethylene Terephthalate Glycol-Modified (PET-G) shrink wrap.

Table 1: XTRA4 ingredients and their functions

Ingredient	Function
Sodium hyaluronate	Control of corneal thickness (deswelling agent)
Minimum Essential Medium (MEM)	Buffering agents
Recombinant human serum albumin	Cell metabolism enhancer
Sodium bicarbonate	pH adjustment
Sodium pyruvate	Energy source for endothelial cell viability
Streptomycin sulfate	Antibiotic
Gentamicin sulfate	Antibiotic
Purified water	Vehicle

Substantial Equivalence Discussion

Table 2 reports a comparison of technological characteristics of XTRA4 and Optisol-GS medical devices.

Parameter	Device: XTRA4	Predicate device: Optisol-GS	Difference
1. FDA registration reference number	K251320	K924165	
2. How used			
a. Intended use	Corneal storage media	Corneal storage media	None
b. Indications for use	XTRA4 is a corneal storage solution for storage of human cornea suitable for keratoplasty for up to 14 days under refrigeration (2-8°C)	Storage of human corneas suitable for keratoplasty for up to 14 days under refrigeration (2-8°C)	None
c. Principle of operations	Provides basic nutrients for cell maintenance during storage of donor corneas at 2°C – 8°C for up to 14 days, and prevents tissue swelling by preserving corneal thickness	Provides basic nutrients for cell maintenance during storage of donor corneas at 2°C – 8°C for up to 14 days, and prevents tissue swelling by preserving corneal thickness	None
d. Type of Contact	Indirect contact (explanted corneal tissue)	Indirect contact (explanted corneal tissue)	None
e. Where Used	Eye Banks, hospitals, surgical facilities	Eye Banks, hospitals, surgical facilities	None
f. Uses	Single use	Single use	None
3. Packaging/How Supplied	glass vial with screw cap top	glass vial with screw cap top	None
4. Key Ingredients of the solution	Hyaluronic acid as osmotic agent, recombinant human serum albumin (rHSA) as a cell metabolism enhancer and gentamycin sulfate and streptomycin sulfate as antibiotics	Dextran and chondroitin sulfate as osmotic agents, polypeptides as cell metabolism enhancers and gentamycin sulfate and streptomycin sulfate as antibiotics	Similar (both contain osmotic agents, cell metabolism enhancers and gentamycin sulfate and streptomycin sulfate as antibiotics)
5. Sterility	Sterile	Sterile	Both are provided sterile
6. Bacterial endotoxins	<i>Limulus amoebocyte</i> lysate (LAL) test ; Spec. (< 0.5 EU/ml)	<i>Limulus amoebocyte</i> lysate (LAL) test; Spec. Unknown	
7. Shelf-life	24 months	24 months	None
8. Storage	2°C – 8°C	2°C – 8°C	None
9. Performance	Demonstrated to be equivalent to predicate device at storing corneas for up to 14 days when stored at 2°C – 8°C	Corneal storage at 2°C – 8°C up to 14 days	None

Performance Data

XTRA4 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.

A biological evaluation was conducted per FDA's Biocompatibility Guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" (<https://www.fda.gov/media/142959/download>), and included detailed material characterization and processing.

In addition, the finished sterile XTRA4 device underwent biocompatibility testing (per ISO 10993-1) including:

- Cytotoxicity test according to UNI EN ISO 10993-5:2009
- Ocular irritation test according to ISO 10993-23:2021
- Guinea pig maximization test (GPMT) - according to ISO 10993-10:2021

These tests determined that the finished sterile device did not cause cytotoxicity, ocular irritation or sensitization.

XTRA4 is a solution manufactured and sterilized by sterile filtration using 0.2-micron polyethersulfone membrane filters. The filters have been validated for both compatibility and bacterial retention to ensure a Sterility Assurance Level (SAL) of 10^{-6} . Each sterilizing filter is integrity-tested according to specific parameters defined during the process validation phase. Each batch is also tested for sterility prior to release. A finished product endotoxin specification for XTRA4 of < 0.5 EU/ml has been established and batch results confirm that XTRA4 conforms with this specification according to LAL testing per USP.

The vial caps are sterilized by Gamma irradiation and the vials are sterilized by depyrogenation process ($230^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for 52 min). The shelf life for XTRA4 is 24 months when stored at 2°C to 8°C .

Package integrity testing was performed during process validation for primary packaging (vials and caps) by container closure test according to USP <1207.2> on representative samples, evaluating the ability of the packaging to maintain the sterile barrier when challenged by submersion in a solution

contaminated by the reference strain *Brevundimonas diminuta* at a concentration $\geq 10^5$ CFU/ml. In addition, transport simulation testing according to ASTM D4169 and ISTA3A was performed and demonstrated compliance of each level of packaging.

XTRA4 was demonstrated in an *in vitro* study to be equivalent to the predicate device Optisol-GS in storage of corneas for 14 days at 2-8°C in comparison to the predicate device Optisol-GS. In this prospective study, paired donor corneas were obtained and respectively stored in XTRA4 and in the predicate Optisol-GS. The assessments to determine equivalent performance were endothelial cell loss, endothelial cell density (ECD), coefficient of variation, and percentage hexagonality on days 1 and 14. The results indicated that XTRA4 adequately preserved the cornea for up to 14 days in storage at 2-8°C and had similar performances in preserving corneal endothelium cell structural integrity and functionality as compared to Optisol-GS. Similar to the reference device, the *ex vivo* testing is adequate for establishing substantial equivalence.

Conclusion

XTRA4 is substantially equivalent to the predicate device Optisol-GS in terms of design features, technological characteristics, indications for use, safety and effectiveness. Additionally, substantial equivalence was demonstrated through *ex vivo* performance testing on human corneas.