DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 6, 2015

Eurobio
% Ms. Jessica Barrett
International Medical
4733 Millrace Lane
Murray, UT 84107

Re: K151061
Trade/Device Name: Cornea Cold®
Regulation Number: N/A
Regulation Name: N/A
Regulatory Class: Unclassified
Product Code: LYX
Dated: June 2, 2015
Received: June 10, 2015

Dear Ms. Barrett:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Y. Alexander -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151061

Device Name
Cornea Cold

Indications for Use *(Describe)*
Hypothermic (2-8°C) human corneal storage for 14 days

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

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Date prepared: July 29 2015.

Trade name: Cornea Cold®

Common name of the device: Hypothermic corneal storage media
Product Code: LYX
Device class: Unclassified

Substantial equivalence
The current device is substantially equivalent to Optisol-GS Corneal Storage Media from Chiron Intraoptics/Bausch& Laumb- 510(K) number: K924165

Description of the device
Functioning of the device: Cornea Cold® is a sterile hypothermic corneal storage medium intended for human corneal storage at 2-8°C, for up to 14 days. Corneas are directly placed in Cornea Cold® storage

medium after surgery, and stored in eye banks between +2°C and +8°C for a maximum of 2 weeks. The shortest storage time is determined by the time needed to obtain serology results of the donor. It is for single use, to be used by physicians or highly skilled personnel such as bank operators. The device gets into direct contact with the patient by accumulation in the cornea graft.
Under aseptic conditions, the seal of the vial is broken and the cap loosened. The cap is lifted and place adjacent to sterile field with inner liner face up. The cornea is then transferred into the vial and submerged with liquid. The cap is tightened.

Scientific basis for the device: 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. Cornea Cold® hypothermic corneal storage media contains Dextran, an osmotic agent. The device contains the necessary components for preservation of cornea for grafting, with antibiotics to prevent microbiological contaminations, and other components (essential and non essential amino acids, energetic components, vitamins, pH indicator, inorganic salts) to maintain the cornea in healthy state for keratoplasty.
Storage of cornea in these conditions can last up to 14 days.

Physical and performance characteristics:

Device design and Material used: Cornea Cold® medium (28 mL/vial) is contained in a 30 ml type I glass vial and the cap has a seal to ensure the vial has not been opened. The device comes as single unit (Ref: CMXCOLD4FB). Twelve individual Cornea Cold® units are packaged in a box (Ref: CMXCOLD4FB-UN), appropriately labeled with lot number and expiration date. Cornea Cold® is ready to use and instructions for Use are included in the box.

Physical properties: Cornea Cold® can be stored at 2-8°C until ready for use for up to 9 months. No defrosting of the medium is needed. pH is physiological and osmolarity are controlled. The red cherry color of the medium can be visually monitored in case of abnormal change in pH as indicated in Instruction for use package insert.

Intended use
Hypothermic (2-8°) human corneal storage for 14 days.

Technological characteristics compared to the predicate device
Cornea Cold® has the same technological characteristics as the predicate device, contains Dextran as deswelling agent. Like Optisol-GS, the medium is a sterile solution in a glass vial.

Summary of substantial equivalence highlighting similarities and differences

Feature	Optisol-GS (predicate device K924165)	Cornea Cold	Comment if different from predicate device
Intended use	Hypothermic corneal storage	Hypothermic corneal storage	
Indications for use	Hypothermic (2-8°C) human corneal storage for 14 days	Hypothermic (2-8°C) human corneal storage for 14 days	
Target population	Cornea for keratoplasty	Cornea for keratoplasty	
Where used	Eye bank, hospital	Eye bank, hospital	
Energy used	Refrigeration 2-8°C	Refrigeration 2-8°C	
Design	Single use individual glass vials sold in a package of 12	Single use individual glass vials sold in a package of 12	
Performance		Substantially equivalent to predicate device	
Standards	Sterile apyrogenic solution	Sterile apyrogenic solution	

Materials	Glass vial/ Dextran and chondroitin sulfate as osmotic agents/ gentamycin streptomycin antibiotics	Glass vial/Dextran as osmotic agent/penicillin streptomycin antibiotics	Cornea Cold. Dextran alone at 6% was found to be an efficient and safe deswelling agent. Penicillin and Streptomycin have been chosen for their abilities to have a broad spectrum of activity.
Biocompatibility		Full biocompatibility testing was done; interaction between container and content was negative; cornea in Cornea Cold were of as good or better quality than in Optisol-GS	
Sterility	Sterile	Sterile	
Others (electrical, mechanical, chemical, thermal, radiation safety)	Not applicable	Not applicable	

Assessment of substantial equivalence

Non-clinical tests:

- Physicochemical tests (pH, osmolarity)
- Microbiological tests (endotoxins)
- Stability tests (physicochemical parameters, biological parameters) at temperature of storage and extreme temperatures
- Interaction container/content
- Biocompatibility
    . Cytotoxicity
    . Ocular irritation test
    . Sensitization test
    . Bacterial reverse mutation test (Ames test)

Clinical tests: Not required

Comparison with predicate device: Comparative analyses were performed on various typical morphological, structural and physiological parameters of paired, preserved eye bank corneas between the subject and predicate device.

Conclusion: Cornea Cold is substantially equivalent to the predicate device