K063304

Life4°C 510(k) SUMMARY

(510(K) Summary, Required Under 21 CFR 807.87(h))

DATE PREPARED: 10/30/06

COMPANY (APPLICANT) NAME AND ADDRESS

Numedis, Inc.
2 Enterprise Avenue NE #A2
Isanti, Minnesota 55040
U.S.A.
Telephone Number: 763-444-9441
Fax Number: 763-444-9364
Email: ibio@earthlink.net

Contact Name: President: Debra L. Skelnik

Official Correspondent:

Mary Ellen Freddo (Official Correspondent)
Telephone Number: 603-661-3716
Fax Number: 413-306-4707
Email: mefreddo@ttlc.net
QS/RA Senior Executive Consulting
188 Bumstead Road
Monson, MA 01057
U.S.A.

DEVICE INFORMATION

Proprietary Name	LIFE4°C
Common Names	Sterile medium for hypothermic corneal storage
Classification Names	LYX Media, Corneal Storage

Device Classification Information

Regulatory Class:	Unclassified
Product codes:	LYX

Substantial equivalence

Life4°C is substantially equivalent to Optisol GS Corneal Storage Media, K924165 in indications, design, performance, safety and biocompatibility profiles.

Predicate Device

Trade Name:	Optisol GS Corneal Storage Media
Company:	Chiron Intraoptics
510(k) #:	K924165
Date Approved:	October 6, 1992

Intended Use

Life4°C is indicated for storage of human corneas suitable for keratoplasty up to 14 days under refrigeration (2-8°C).

Device Description and Principles of Operation

Life4°C is sterile, non-pyrogenic, advanced buffered corneal preservation medium which is supplemented with chondroitin sulfate (membrane stabilizer), recombinant human insulin (cell metabolism enhancer), Dextran (osmotic agent), glutathione (antioxidant, free-radical scavenger, enzyme cofactor), stabilized L-glutamine , ATP precursors, nutrient cell supplements, amino acids, vitamins, trace elements, gentamycin, streptomycin and phenol red (pH indicator).

Materials Used in the Device and Its Components, Including Packaging

Life4°C is a formulated, sterile, 30 ml corneal storage solution for single use. Life4°C is individually packaged in a 30 ml PETG bottle with a HDPE cap and tamper seal. Each Life4°C unit is appropriately labeled with lot number and expiration date. Twelve individual Life4°C units are packaged in a PET clamshell with a tamper seal, that is appropriately labeled with lot number and expiration date. Life4°C Instructions for Use are included in the clamshell. The 12 unit clamshell is placed into an outer labeled paperboard box for shipping.

Performance Data

(a) Non-clinical tests

The following tests have been done on Life4°C:

1. Long-term Stability
2. Safety Testing
3. Performance Characteristics
4. Sterilization Validation
5. Comparison with Predicate Device
6. Package Validation

(b) Clinical tests

Not required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 1 2007

Numedis, Inc.
c/o Ms. Mary Ellen Freddo
QS/RA Senior Executive Consulting
188 Bumstead Rd.
Monson, MA 01057

Re: K063304
Trade/Device Name: Life4°C
Regulatory Class: Unclassified
Product Code: LYX
Dated: December 6, 2007
Received: December 6, 2007

Dear Ms. Freddo:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Indications for Use

510(k) Number (if known): K063304

Device Name: LIFE4°C

Indications for Use:

LIFE4°C is indicated for storage of human corneas suitable for keratoplasty up to 14 days under refrigeration (2-8°C).

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

Ph. D.

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K063304