K032422

DEC 1 5 2003

AL.CHI.MI.A. S.r.l
510(k) Submission
EUSOL-C

510(k) Summary

(1) Submitter Information

Name: AL.CHI.MI.A. S.r.l.

Address:

Viale Europa 12/A
35020 Ponte San Nicolò (PD)
ITALY

Telephone Number: 39-049-8962074/64

Contact Person:

Dr. George Myers (Official Correspondent)
Medsys Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604
Telephone 201-727-1703
Fax 201-727-1708

Date Prepared: May 19, 2003

(2) Name of Device

Trade Name: Eusol-C
Common Name: Sterile medium for hypothermic corneal storage
Classification name: Not classified

(3) Equivalent legally-marketed devices.

Optisol-GS Corneal Storage Media, K924165

(4) Description

Eusol-C is sterile medium for hypothermic corneal storage intended for corneal storage at 4°C for up to 14 days. It is to be used by physicians or highly skilled personnel, such as Eye Bank operators.

(5) Intended Use

Eusol-C is indicated for corneal storage for up to 14 days.

(6) Performance Data

(a) Non-clinical tests

The following tests have been done on Eusol-C:

1. Long-term stability and Accelerated aging
2. Container closure test
3. Performance characteristics
4. Sterilization Validation
5. Comparison with Predicate Device

(b) Clinical tests

Not required.

(c) Conclusions

Eusol-C is equivalent in safety and efficacy to the legally-marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2003

AL.CHI.MI.A. S.r.l
c/o George Myers, Ph.D.
Medsys, Inc.
377 Route 17 S
Hasbrouck Heights, NJ 07604

Re: K032422
Trade Name: Eusol-C
Regulation Number: Unclassified
Product Code: LYX
Dated: November 5, 2003
Received: November 6, 2003

Dear Dr. Myers:

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 Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Page 1 of 1

510(k) Number (if known):_____

Indications for Use Form

Device Name: Eusol-C

Indications for Use:

Eusol-C is indicated for the storage of donor corneas for up to 14 days.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K032422