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K991421

Irvine Scientific

April 20, 1999

IRVINE SCIENTIFIC™

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by:

Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705-5588

Telephone: (800) 437-5706
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Contact: Roberta L. Johnson

Date Submitted: April 20, 1999

Device Identification:

Trade Name:	Freezing Medium TEST Yolk Buffer (TYB) with Glycerol Refrigeration Medium TEST Yolk Buffer (TYB)
Common Name:	Preservation medium for human semen
Classification Name:	Reproductive Media (21 CFR, 886.6180)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335

Description:

Freezing Medium – Test Yolk Buffer (TYB) with Glycerol and Refrigeration Medium – Test Yolk Buffer (TYB) are synthetic, defined media intended for use in assisted reproductive technology procedures that specifically require donor semen samples to be stored at low temperatures, either under refrigeration or frozen..

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Intended Use:

TYB Freezing Medium with Glycerol is intended for the cryopreservation of human semen samples prior to use in assisted reproductive technology procedures. TYB Refrigeration Medium is intended to protect human semen samples during refrigerated storage prior to use in assisted reproductive technology procedures.

Technological Characteristics:

TYB Freezing Medium with Glycerol and TYB Refrigeration Medium have utility for those situations where semen must be stored prior to use in assisted reproductive procedures such intrauterine insemination, in vitro fertilization or intracytoplasmic sperm injection (ICSI). TYB Freezing Medium with Glycerol is designed to protect semen samples during frozen storage, while TYB Refrigeration Medium is designed to protect semen samples during refrigerated storage.

Performance Data:

TYB Refrigeration Medium and TYB Freezing Medium with Glycerol will be assayed by a sperm recovery assay prior to release to market. The assay will ensure that the product functions appropriately and that no toxic components are present in the formulation. TYB Refrigeration Medium and TYB Freezing Medium with Glycerol have been used in a variety of clinical settings, for their intended use for a number of years. In that time, the products have become the standard media used for the low temperature storage and preservation of human semen samples.

Additional Information:

A sperm recovery assay will be performed as a condition of release for these products, as well as endotoxin and sterility testing. Results of all release assays performed will be reported on a lot-specific certificate of analysis, and will be indicated on the labeling.

Conclusion:

The conclusion from performance testing, as well as a review of the historical information contained in professional literature shows that TYB Freezing Medium with Glycerol and TYB Refrigeration Medium are suitable for their intended use, and meet the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Roberta L. Johnson
Manager, Regulatory Affairs
Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705-5588

Re: K991421
Freezing Medium TEST Yolk Buffer (TYB) with Glycerol; Refrigeration Medium TEST Yolk Buffer (TYB)
Dated: April 22, 1999
Received: April 23, 1999
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Ms. Johnson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K991421

Device Name: FREEZING MEDIUM AND REFRIGERATION MEDIC

Indications for Use:

Refrigeration Medium – Test Yolk Buffer and Freezing Medium – Test Yolk Buffer with Glycerol are intended for use in assisted reproductive technology procedures that involve the manipulation and storage of semen samples prior to use in in vitro fertilization and other similar treatments. Refrigeration Medium – Test Yolk Buffer is specifically designed for to protect semen samples during refrigerated storage, while Freezing Medium – Test Yolk Buffer with Glycerol is intended to be used as a cryopreservative of semen samples.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Legan

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991421

Prescription Use ✓
(Per 21 CFR 801.109)