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

Submitted by: Irvine Scientific Sales Co., Inc.
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Contact: Wendell Lee, PhD.

Date Submitted: January 27, 2000

Device Identification:

Trade Name:	Embryo Freeze Media Kit Embryo Thaw Media Kit
Common Name:	Embryo cryopreservation media Embryo thawing and recovery media
Classification Name:	Reproductive Media (21 CFR, 884.6180)

Predicate Device:

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

Description:

The five media that comprise the two kits, Embryo Freeze Media Kit and Embryo Thaw Media Kit are all based upon the formulation of modified human tubal fluid (K983586). The two media in the Embryo Freeze Media kit

are intended to be used sequentially, for the preparation for, and cryopreservation of, human blastocysts. The first medium to be used, F1, which is used in preparation for freezing, contains 1.5M PROH. The second medium, F2, to be used during cryostorage, containing 1.5M PROH and 0.1M sucrose. Both F1 and F2 are also supplemented with human serum albumin (HSA).

The three media in the Embryo Thaw Media kit are also intended for sequential use in the thawing and recovery of cryopreserved human embryo. The first medium used in the thawing process, T1, contains 1.0M PROH and 0.2M sucrose. The second medium, T2 contains 0.5M PROH and 0.2M sucrose. T3 contains 0.2M sucrose. Each T1, T2 and T3 contain HSA. All five media contain gentamicin sulfate.

Intended Use:

The Embryo Freeze Media Kit is intended for use in the preparation for, and cryopreservation of, human Cleavage Stage (C-S) embryos. The Embryo Thaw Media Kit is intended for use in the thawing and recovery of cryopreserved human embryos.

Technological Characteristics:

Embryos are routinely stored for use in future assisted reproductive procedures. In some instances, excess eggs will be retrieved from the patient, and fertilized. If development of these fertilized eggs indicates a potential for viability during implantation, they may be frozen for future use. In the event that the current transfer is unsuccessful, and does not result in a clinical pregnancy, the patient has embryos in reserve that may be used for implantation in future procedures. Embryos are also routinely frozen when patients have a history of unsuccessful implantation procedures, and also for those patients who desire multiple children. Media to protect the embryos during the preparation for cryopreservation, during

The media in the Embryo Freeze Media Kit, F1 and F2 are designed to be used sequentially for the preparation of embryos for cryopreservation, and as the protective media during cryostorage. The media in the Embryo Thaw Kit, T1, T2 and T3 are also designed for sequential use, in the thawing and recovery of cryopreserved human embryos. None of the media are intended to contact the patient.

Performance Data:

The Embryo Freeze Media Kit and the Embryo Thaw Media kit have been studied by five independent field laboratories, using mouse embryos and the protocol for embryo freezing, thawing and recovery presented in the product inserts for these kits. The conclusion from all laboratories that evaluated the kits was that the Embryo Freeze Media kit and Embryo Thaw Media kit performed at least as well as the control freeze/thaw media in use in the laboratories.

Additional Information:

Endotoxin, mouse embryo freezing and recovery assay performance and sterility tests will be performed as a condition of release for these products. 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 results from the field testing of these products demonstrates that Embryo Freeze Media Kit and Embryo Thaw Media kit 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

JAN 1 8 2002

Wendell Lee, Pharm.D.
Vice President
Quality Systems and Regulatory Affairs
Irvine Scientific Sales Co., Inc.
2511 Daimler Street
SANTA ANA CA 92705-5588

Re: K013518
Trade/Device Name: Embryo Freeze Media Kit and Embryo Thaw Media Kit
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: October 18, 2001
Received: October 23, 2001

Dear Mr. Lee:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

INDICATIONS FOR USE STATEMENT (page 1 of 2)

510(K) Number: K013518

Device Name: Embryo Freeze Media Kit; Embryo Thaw Media Kit

Indications for Use:

Embryo Freeze Media Kit is intended for use in the assisted reproductive procedure, of embryo cryopreservation. The two media kit is designed to protect human cleavage-stage embryos during rapid freezing procedures and during frozen storage.

Embryo Thaw Media Kit is intended for use in the assisted reproductive procedure of thawing frozen cleavage-stage embryos. The three media kit is designed to protect human cleavage-stage embryos during warming and thawing after cryopreservation.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K013518

Prescription Use ✓