K060168

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

Submitted by:

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

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Contact: Wendell Lee, Pharm.D.

APR 24 2006

Date Submitted: December 22, 2005

Device Identification:

Trade Name:	Vit Kit™ - Freeze Blastocyst Vitrification Freeze Kit Vit Kit™ - Thaw Blastocyst Vitrification Thaw Kit
Common Name:	Blastocyst Vitrification cryopreservation media Blastocyst Vitrification thawing and recovery media
Classification Name:	Reproductive Media (21 CFR, 886.6180)

Predicate Device:

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

Description:

The five (5) media that comprise the two kits, Vit Kit™ - Freeze and Vit Kit™ - Thaw are all based upon the modified formulation of Medium 199. The Medium 199 is HEPES buffered and contains 20% (v/v) SSS, 35μg/mL gentamicin and varying concentrations of DMSO, EG and sucrose. The two (2) freeze, ES and VS, media in the Vit Kit™ - Freeze are intended to be used sequentially, for the preparation for, and cryopreservation of, human blastocysts. ES is used in preparation for freezing and contains 7.5 % (v/v) DMSO and EG. VS is to be used during cryostorage and contains 15% (v/v) DMSO and EG and 0.5M sucrose.

Blastocyst Vitrification Freeze Kit
Blastocyst Vitrification Thaw Kit

The three (3) thaw, TS, DS and WS, media in the Vit Kit™ - Thaw are also intended for sequential use in the thawing and recovery of cryopreserved human embryo. The first medium used in the thawing process, TS, contains 1.0M sucrose. The second medium, DS, contains 0.5M sucrose. The third medium, WS, contains no sucrose.

Intended Use:

Vit Kit™ - Freeze is intended for ultra-rapid freezing and containment of human blastocysts for Assisted Reproductive Technology (A.R.T.) procedures. This kit is designed for use with Irvine Scientific's Blastocyst Vitrification Thaw Kit (Vit Kit™ - Thaw, Catalog #90137) for optimal recovery of specimens.

Vit Kit™ - Thaw is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using Irvine Scientific's Blastocyst Vitrification Freeze Kit (Vit Kit™ - Freeze, Catalog #90133) for Assisted Reproductive Technology (A.R.T.) procedures.

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 storage, and ultimate thawing and recovery are, therefore, different in composition from media used for gamete retrieval, during fertilization and implantation.

The media in the Vit Kit™ - Freeze, ES and VS, are designed to be used sequentially for the preparation of vitrified embryos for cryopreservation, as the protective media and containment during cryostorage.

The media in the Vit Kit™ - Thaw, TS, DS and WS, are also designed for sequential use, in the thawing and recovery of cryopreserved vitrified human embryos. None of the media are intended to contact the patient.

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. Refer to **Appendix B**.

Conclusion:

The results from the field testing (refer to **Appendix D**) of these products along with the peer reviewed articles (refer to **Attachment 1** and **Attachment 2**) that were presented demonstrates that Vit Kit™ - Freeze and Vit Kit™ - Thaw 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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Wendell Lee, Pharm.D.
Vice President
Irvine Scientific Sales Co., Inc.
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SANTA ANA CA 92705-5588

APR 2 4 2006

Re: K060168
Trade/Device Name: Vit Kit™ - Freeze
Blastocyst Vitrification Freeze Kit
Vit Kit™ - Thaw
Blastocyst Vitrification Thaw Kit
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: January 20, 2006
Received: January 24, 2006

Dear Dr. 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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.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

Enclosure

INDICATIONS FOR USE STATEMENT

510(K) Number: K060168

Device Name: Vit Kit™ - Freeze
Blastocyst Vitrification Freeze Kit

Indications for Use:

Vit Kit™ - Freeze is intended for ultra-rapid freezing and containment of human blastocysts for Assisted Reproductive Technology (A.R.T.) procedures. This kit is designed for use with Irvine Scientific's Blastocyst Vitrification Thaw Kit (Vit Kit™ - Thaw, Catalog #90137) for optimal recovery of specimens.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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 K060168

INDICATIONS FOR USE STATEMENT

510(K) Number: K060168

Device Name: Vit Kit™ - Thaw
Blastocyst Vitrification Thaw Kit

Indications for Use:

Vit Kit™ - Thaw is intended for the recovery of human blastocysts that have undergone ultra-rapid freezing and containment using Irvine Scientific's Blastocyst Vitrification Freeze Kit (Vit Kit™ - Freeze, Catalog #90133) for Assisted Reproductive Technology (A.R.T.) procedures.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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
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