K072607
pg. 1 of 3

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
Facsimile: (949) 261-6522

JAN 25 2008

Contact: Wendell Lee

Date Submitted: September 14, 2007

Device Identification:

Trade Name:	Lyophilized Early Cleavage Medium (ECM) Kit
Common Name:	In vitro embryo culture medium
Product Code:	MLQ
Classification Name:	Reproductive Media (21 CFR, 884.6180)

Predicate Device:

Early Cleavage Medium (K033462)

Description:

Lyophilized Early Cleavage Medium Kit is a synthetic, defined medium composed of a balanced mixture of salts and other nutrient substances designed to support early stages of embryonic growth (up to three days post-fertilization).

Intended Use:

Lyophilized Early Cleavage Medium Kit is intended for assisted reproductive technology (ART) that involves the manipulation of gametes and embryos. Specifically Lyophilized Early Cleavage Medium Kit is intended for use as a culture medium through day three (3) of embryo development.

Technological Characteristics:

After retrieval of oocytes from the patient, the oocytes are placed in a culture dish containing the reconstituted Lyophilized Early Cleavage Medium and the desired type and amount of protein supplementation. Fertilization is allowed to take place, and the zygote is removed to a fresh dish containing fresh Lyophilized Early Cleavage Medium and protein. This culture dish is placed into a carbon dioxide incubator, and the embryo is allowed to develop, in vitro, until the desired stage of development has been achieved, usually up to three days post fertilization. At that time, the embryo may be transferred to the patient, or to a second, more complex medium for continued growth.

Performance Data:

The Lyophilized Early Cleavage Medium Kit is assayed by mouse embryo assay prior to release to market. This assay assures that the product is both functional for its intended use, the support of embryonic growth, and that no toxic components are present in the formulation. Parallel mouse embryo studies have been performed on Early Cleavage Medium (K033462) and P-1 (K983589) to assure the performance of the Lyophilized Early Cleavage Medium Kit. These studies are similar to those previously performed, and submitted for the 510(k) of Early Cleavage Medium (K033462) and P-1 (K983589).

Additional Information:

Mouse embryo testing will be performed as a condition of release for these products, as well as endotoxin and sterility testing. Results of all release

K072607
Pg. 3 of 3

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 the Lyophilized Early Cleavage Medium Kit is suitable for its intended use, and meet the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335. References are presented in Appendix F of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 25 2008

Wendell Lee, Pharm.D.
Vice President
Regulatory Affairs/Quality Systems
Irvine Scientific Sales Company, Inc.
2511 Daimler Street
SANTA ANA CA 92705

Re: K072607
Trade Name: Lyophilized Early Cleavage Medium (ECM) Kit
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: January 3, 2008
Received: January 4, 2008

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, 1796, 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 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" (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,

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 (page 1 of 1)

510(K) Number: 072607

Device Name: Lyophilized Early Cleavage Medium Kit

Indications for Use:

Lyophilized Early Cleavage Medium Kit is for use in assisted reproduction technology (ART) that involved the manipulation of gametes or embryos. Specifically, Lyophilized Early Cleavage Medium Kit is intended for use as a culture medium from fertilization through day three (3) of embryo development.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K072607