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

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

Date Submitted: October 31, 2003

Device Identification:

Trade Name:	Early Cleavage Medium (ECM)
Common Name:	In vitro embryo culture medium
Classification Name:	Reproductive Media (21 CFR, 886.6180)

Predicate Device:

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

Description:

Early Cleavage Medium 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).

K033402

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Intended Use:

Early Cleavage Medium is intended for assisted reproductive procedures that involve the manipulation of gametes and embryos. These procedures include the use of Early Cleavage Medium as a culture medium through day three of development.

Technological Characteristics:

After retrieval of oocytes from the patient, the oocytes are placed in a culture dish containing 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 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:

Early Cleavage Medium 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 P-1 and ECM to assure the performance of ECM. These studies are similar to those previously performed, and submitted for 510K of P-1 Medium (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

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 Early Cleavage Medium is suitable for its 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 5 2004

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: K033462
Trade/Device Name: Early Cleavage Medium (ECM)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media
and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: October 31, 2003
Received: October 31, 2003

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

Enclosure

Indications for Use

510(k) Number (if known): K033462

Device Name: Early Cleavage Medium (ECM)

Indications For Use:

Early Cleavage Medium (ECM) is intended for use in assisted reproductive procedures, which include gamete and embryo manipulation. These procedures include the use of ECM as a culture medium through day 3 of 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)

David A. Lyon

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033462