

2/18/99

Irvine Scientific

K983589

October 9, 1998



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  
Facsimile: (949) 261-6522

Contact: Roberta L. Johnson

Date Submitted: October 9, 1998

**Device Identification:**

Trade Name: P-1® (Preimplantation Stage One) Medium  
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:**

P-1 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). P-1 has been formulated without glucose and phosphate, which may be detrimental to blastocyst development. P-1 may be used as a stand-alone medium, or as the first stage of a sequential medium protocol.

**Intended Use:**

P-1 is intended for assisted reproductive procedures that involve the manipulation of gametes and embryos. These procedures include the use of P-1 as a culture medium through day three of growth.

**Technological Characteristics:**

After retrieval of oocytes from the patient, the oocytes are placed in a culture dish containing P-1 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 P-1 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:**

P-1 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. P-1 has been used in a variety of clinical settings, for its intended use, for a number of years. In that time, the product has become the standard media used for the early development of human embryos in vitro.

**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 P-1 is suitable for its intended use, and meet the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.

**PROPOSED LABELING**

Three copies of the proposed labeling for P-1 are enclosed with this submission, beginning on the following page. These labels include vial/bottle labels, and the proposed package insert. Some information, such as results of endotoxin tests and mouse embryo assays, will be included in the lot-specific certificate of analysis provided with the product. An example of the format for these certificates of analysis, and of the information supplied in them, may be found in Appendix C to this submission.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 18 1999

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

Re: K983589  
P-1@ (Pre-implantation Stage One) Medium  
Dated: January 14, 1999  
Received: January 19, 1999  
Regulatory Class: II  
21 CFR 884.6180/Procode: 85 MQL

Dear Ms. Johnson:

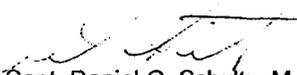
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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: K983589

Device Name: P-1® (Preimplantation Stage One) Medium

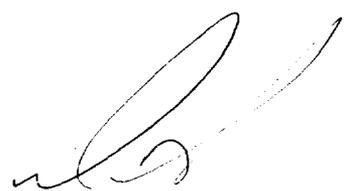
**Indications for Use:**

P-1® medium is intended for use in assisted reproductive technology procedures that involve the manipulation of gametes or embryos. Specifically, P-1® is intended for use as a culture medium through day three of embryo development.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use



(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices

510(k) Number K983589/S001