JUL - 2 1999

Irvine Scientific

April 20, 1999

IRVINE SCIENTIFIC™

K991420

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: April 20, 1999

Device Identification:

Trade Name:	Sperm Washing Medium Modified Sperm Washing Medium
Common Name:	Sperm processing media
Classification Name:	Reproductive Media (21 CFR, 886.6180)

Predicate Device:

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

Description:

Modified Ham's F-10 with Albumin is synthetic, defined media composed of a mixture of salts and other physiologically compatible substances. Modified Ham's F-10 with Albumin contains 5 mg/mL of human serum albumin.

Intended Use:

Modified Ham's F-10 with Albumin is intended for use in assisted reproductive procedures such as sperm washing.

Technological Characteristics:

Modified Ham's F-10 with Albumin is used to purify and concentrate sperm prior to use in assisted reproductive procedures. The goal of such sperm "washing" procedures is to concentrate and purify viable sperm, and separate them from the non-sperm constituents of seminal fluid, simulating the filtering effect of cervical mucous. A higher concentration of viable sperm increases the chance of successful insemination, either in vitro, or intra-uterine. When performed with a culture medium such as Modified Ham's F-10 with Albumin, semen is suspended in the medium, centrifuged to concentrate the viable sperm, and the supernatant, containing seminal debris, is removed. The sperm pellet is then resuspended in fresh medium, and recentrifuged. During this process, viable sperm are concentrated in the medium, and are then aspirated and used for the fertilization procedure.

Performance Data:

Modified Ham's F-10 with Albumin is assayed by mouse embryo assay prior to its release to market. This assay assures that the product contains no toxic components. Modified Ham's F-10 with Albumin has been used in a variety of clinical settings, for its original, intended use, for a number of years. In that time, the product had become an standard alternative media used for the processing of human sperm prior to assisted reproductive procedures.

Additional Information:

Mouse embryo testing will be performed as a condition of release for this product, 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 history of satisfactory use for sperm processing prior to intrauterine insemination, shows that Modified Ham's F-10 with Albumin 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

JUL -2 1999

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

Re: K991420
Modified Ham's F-10 with Albumin
Dated: April 22, 1999
Received: April 23, 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: K991420

Device Name: Modified Ham's F-10 with Albumin

Indications for Use:

Modified Ham's F-10 with Albumin is intended for assisted reproduction procedures such as the processing or manipulation of human sperm prior to insemination, in vitro fertilization and intracytoplasmic sperm injection (ICSI) procedures.

(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, ENT, and Radiological Devices
510(k) Number K991420

Prescription Use ✓
(Per 21 CFR 801.109)