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

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Contact: Wendell Lee, Pharm. D.

Date Submitted: May 9, 2001

Device Identification:

Trade Name: Water for Assisted Reproductive Technologies (A.R.T.) Use

Common Name: Water for Assisted Reproductive Technologies (A.R.T.) Use

Classification Name: Reproductive Media (21 CFR 884.6180)

Predicate Device:

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

Description:

Water for Assisted Reproductive Technologies (A.R.T.) Use is a water intended for use in A.R.T. laboratory procedures requiring a non-pyrogenic high purity grade of water.

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Intended Use:

Water for Assisted Reproductive Technologies (A.R.T.) Use is intended for use in A.R.T. laboratory procedures.

Technological Characteristics:

Water for Assisted Reproductive Technologies (A.R.T.) Use is highly purified water of USP WFI grade.

Performance Data:

Water for Assisted Reproductive Technologies (A.R.T.) Use is assayed by mouse embryo assay prior to its release to market. This assay assures that the product will support embryonic growth and that no toxic components are present. The equivalent of Water for Assisted Reproductive Technologies (A.R.T.) Use has been used in a variety of clinical settings for the same intended use for a number of years and has become the standard medium used for the fertilization and growth of human gametes and embryos.

Additional Information:

Mouse embryo, and USP 24 testing will be performed as a condition of release for this product. Results of all release assays performed will be indicated on the labeling and reported on a lot-specific certificate of analysis.

Conclusion:

The conclusion from performance testing as well as a review of the historical information contained in professional literature shows that Water for Assisted Reproductive Technologies (A.R.T.) Use is suitable for the intended use and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335 in addition to showing substantial equivalence to other 510(k) cleared Irvine Scientific products.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 3 2001

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: K011598
Water for Assisted Reproductive Technologies (A.R.T.) Use
Dated: May 9, 2001
Received: May 24, 2001
Regulatory Class: II
21 CFR §884.6170/Procode: 85 MTW

Dear Dr. Lee:

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) 594-4639. 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 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,

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 (s)

Irvine Scientific May 9, 2001

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K011598

Device Name: Water For Assisted Reproductive Technologies (A.R.T.) Use

Water for Assisted Reproductive Technologies (A.R.T.) Use is intended for use in assisted reproductive technology procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K011598

Prescription Use ✓
(Per 21 CFR 801.109)