2/18/99

K983586

Irvine Scientific

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:	HTF Medium Modified HTF Medium-HEPES HTF Powder (without antibiotics) Modified HTF Powder-HEPES (without antibiotics) Modified HTF Powder-HEPES
Common Name:	Gamete and embryo retrieval, storage and transfer medium
Classification Name:	Reproductive Media (21 CFR, 886.6180)

Predicate Device:

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

Description:

HTF and Modified HTF (mHTF) are synthetic, defined media intended for use in assisted reproductive technology procedures. Both have been formulated

2511 Daimler Street • Santa Ana, CA • 92705-5538 • 949-261-7800 • 800-437-5706 • FAX: 949-261-6522 • http://irvinesci.com

to mimic the composition of the fluid found in human fallopian tubes. Modified HTF differs from HTF by the buffer system used. HTF uses a sodium bicarbonate buffering system, and is appropriate for those procedures requiring the use of a carbon dioxide atmosphere during incubation. Modified HTF utilizes a combined sodium bicarbonate/HEPES ([4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid]) buffer. This buffering system provides maintenance of physiological pH (7.2 to 7.4), and does not require the use of a carbon dioxide incubator.

Intended Use:

HTF and modified HTF are intended for the retrieval, culture, transport, storage and transfer of human gametes and embryos.

Technological Characteristics:

Modified HTF is has utility for a variety of assisted reproductive procedures. It has been used for a number of years as a sperm-washing medium. During sperm wash procedures, viable sperm cells are separated from the other constituents of seminal fluid in an effort to concentrate the viable sperm and increase the number available for fertilization. A culture medium, such as modified HTF is used to suspend the semen, the sample is centrifuged to pellet the viable sperm, and, after the supernatant is decanted, the pellet is re-suspended in fresh medium. After a brief incubation during which motile sperm "swim-up" into the fresh medium, the sperm are aspirated and used for the desired fertilization procedure. Modified HTF is also used as an oocyte retrieval medium, in procedures that flush oocytes from the patient's fallopian tubes. Once the oocyte has been retrieved, it is placed into a culture dish with an appropriate amount of culture medium, and fertilized. After fertilization, the embryo is allowed to develop in the culture medium, until an appropriate developmental stage is reached. At that time, the embryo is removed from the incubation dish, placed into an suitable amount of mHTF for transport and

implantation into the patient. Modified HTF is therefore intended for use as a sperm-washing medium, an oocyte retrieval medium, and as a transport and storage medium.

HTF intended for use as a culture medium, with appropriate protein supplementation, for the support of fertilized embryos. Fertilization is also allowed to occur in HTF when in vitro fertilization techniques are used. The fertilized gamete is then allowed to grow in the media and supplement, which are replenished as needed, until the desired state of development, usually up to three days post fertilization. Since HTF utilizes a sodium bicarbonate buffer system, it is intended to be used in those procedures that require a carbon dioxide atmosphere, as is found in the incubators used by assisted reproductive laboratories. Therefore, HTF is primarily used as a medium to support embryo growth, development, and culture in vitro.

Performance Data:

HTF and modified HTF are assayed by mouse embryo assay prior to their 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. HTF and modified HTF have been used in a variety of clinical settings, for their intended use, for a number of years. In that time, the products have become the standard media used for the retrieval, growth, storage and transport of human gametes and embryos.

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 HTF and modified HTF are suitable for their 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 HTF and modified HTF 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 E to this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 18 1999

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

Re: K983586
HTF Medium, Modified HTF
Medium-Hepes, HTF Powder
Dated: January 14, 1999
Received: January 19, 1999
Regulatory Class: II
21 CFR 884.6180/Procode: 85MQL

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: K983586/S1

Device Name: HTF Medium and Modified HTF Medium - HEPES.

Indications for Use:

HTF and Modified HTF are intended for use in assisted reproductive technology procedures that involve the manipulation of gametes or embryos. Specifically, HTF is intended for use as a culture medium for the embryo after fertilization, when used with an incubator, and as a medium to support in vitro fertilization. Modified HTF is intended for use as a sperm-processing medium in washing procedures, as an oocyte retrieval medium, for transport of the embryo, and as a support medium for implantation of the embryo. Both HTF and Modified HTF are intended to simulate the substances found in the human, female reproductive system.

(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 K983586/S001