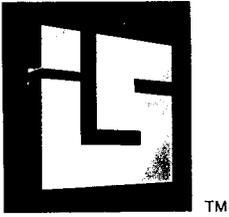


K991419



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

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Contact: Roberta L. Johnson

Date Submitted: April 19, 1999

Device Identification:

Trade Name: Modified Ham's F-10 Basal Medium
Modified Ham's F-10 Basal Medium HEPES
Modified Ham's F-10 Supplement (50X)
lyophilized
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:

Modified Ham's F-10 Basal Medium and Modified Ham's F-10 Basal
Medium HEPES are synthetic, defined media intended for use in assisted
reproductive technology procedures. They are designed to be used with a 50X

lyophilized supplement. Reconstitution of the supplement yields a complete medium. Modified Ham's F-10 Medium differs from Modified Ham's F-10 Medium HEPES by the buffer system used. Modified Ham's F-10 Medium uses a sodium bicarbonate buffering system, and is appropriate for those procedures requiring the use of a carbon dioxide atmosphere during incubation. Modified Ham's F-10 Medium HEPES utilizes a /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:

Modified Ham's F-10 Medium and Modified Ham's F-10 Medium HEPES are intended for the retrieval, culture, transport, storage and transfer of human gametes and embryos.

Technological Characteristics:

Modified Ham's F-10 Medium HEPES has utility for a variety of assisted reproductive procedures, including sperm washing, oocyte retrieval, embryo transfer and implantation and for processing sperm for ICSI procedures. 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 Ham's F-10 Medium HEPES 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 Ham's F-10 Medium HEPES 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 Modified Ham's F-10 Medium HEPES for transport and implantation into the patient.

Modified Ham's F-10 Medium is intended for use as a culture medium, with appropriate protein supplementation, for the support of fertilized embryos. Fertilization is also allowed to occur in Modified Ham's F-10 Medium 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 Modified Ham's F-10 Medium 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.

Performance Data:

Modified Ham's F-10 Basal Medium, Modified Ham's F-10 Basal Medium HEPES and the common 50X lyophilized supplement 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. Modified Ham's F-10 Medium and Modified Ham's F-10 Medium HEPES 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 Modified Ham's F-10 Medium and Modified Ham's F-10 Medium HEPES are suitable for their intended use, and meet the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 1999

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

Re: K991419
Modified Ham's F-10 Basal and 50X Lyophilized
Supplement and Modified Ham's F-10 Basal
Medium HEPES and 50X Lyophilized Supplement
Dated: August 26, 1999
Received: August 30, 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: K991419

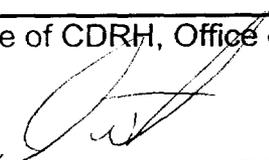
Device Name: Modified Ham's F-10 Basal and 50X Supplement and Modified Ham's F-10 Basal Medium HEPES and 50X Supplement

Indications for Use:

Complete Modified Ham's F-10 Medium and Complete Modified Ham's F-10 Medium HEPES are intended for use in assisted reproductive technology procedures that involve the manipulation of gametes or embryos. Specifically, Complete Modified Ham's F-10 Medium 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. Complete Modified Ham's F-10 Medium HEPES is intended for use as a sperm-processing medium in washing or ICSI procedures, as an cocyte retrieval medium, for transport of the embryo, and as a support medium for implantation of the embryo. Both Modified Ham's F-10 Medium and Modified Ham's F-10 Medium HEPES are supplied to customers as liquid basal media and 50X lyophilized supplements. Users are instructed to reconstitute the lyophilized supplement with the basal liquid media to form the complete media at the time of use.

(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 K991419

Prescription Use 
(Per 21 CFR 801.109)