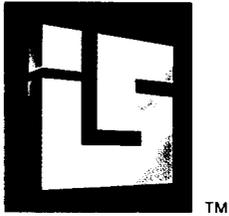


DEC - 6 1999

K991339



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: April 14, 1999

Device Identification:

Trade Name:	Tyrode's Solution, Acidified
Common Name:	zona-drilling reagent for assisted hatching procedures
Classification Name:	Reproductive Media (21 CFR, 886.6180)

Predicate Device:

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

Description:

Tyrode's Solution, Acidified is a synthetic, defined reagent with a pH of 2.1 to 2.5. It is based on the formulation of Tyrode's Solution, a common cell culture medium.

Intended Use:

Tyrode's Solution, Acidified is intended to be used in zona drilling procedures, for assisted hatching.

Technological Characteristics:

Tyrode's Solution, Acidified has been developed with a pH in the range optimal for use in the assisted hatching procedure referred to as zona drilling. In this procedure, the zona pellucida, a noncellular covering over the fertilized ovum is removed by either a chemical or mechanical "drill". This covering must be removed prior to the implantation of the blastocyst, and subsequent pregnancy. A small amount of Tyrode's Solution, Acidified is applied to the zona pellucida of the embryo with an assisted hatching pipette, the embryo observed under a microscope, and when the desired effect has been achieved, the embryo is washed with a neutral medium prior to implantation or further development in vitro. Zona drilling procedures are commonly performed on embryos from older patients, or those with a history of failed assisted reproductive procedures.

Performance Data:

The pH level of each newly manufactured lot of Tyrode's Solution, Acidified is verified prior to release to market. This parameter is the most important for the proper functioning of the product. Lots that do not meet the release specification are not released for sale. In addition, each lot is tested for endotoxin and sterility prior to release. Tyrode's Solution, Acidified 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 reagent used for chemically mediated zona drilling procedures.

Additional Information:

Endotoxin and sterility testing will be performed as a condition of release for this product. 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 Tyrode's Solution, Acidified is suitable for its intended use, and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Ms. Roberta L. Johnson
Manager, Regulatory Affairs
Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705-5588Re: K991339
Tyrode's Solution Acidified (for zona-drilling procedures)
Dated: September 3, 1999
Received September 7, 1999
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Ms. Johnson:

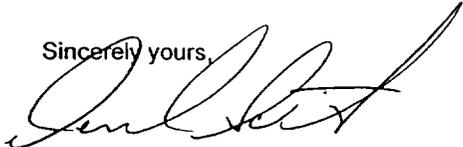
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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: K991339

Device Name: Tyrode's Solution, Acidified

Indications for Use:

Tyrode's Solution, Acidified is intended for use in assisted reproductive procedures involving the manipulation of embryos. Specifically, Tyrode's Solution, Acidified, is intended for use in zona-drilling procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____
(Per 21 CFR 801.109)

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

510(k) Number K991339