JUL -8 1999

K991342

IRVINE SCIENTIFIC™

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by: Irvine Scientific Sales Co., Inc.
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Contact: Roberta L. Johnson

Date Submitted: October 9, 1998

Device Identification:

Trade Name:	PBS 1X
Common Name:	Dulbecco's Phosphate Buffered Saline Solution
Classification Name:	Reproductive Media (21 CFR, 886.6180)

Predicate Device:

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

Description:

PBS 1X is a defined mixture of salts in a physiologic buffer designed to be used as an oocyte retrieval medium, for the short term "bench-top" maintenance of oocytes prior to manipulation, and for the transport of fertilized embryos during implantation procedures.

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Intended Use:

PBS 1X is intended for use in assisted reproductive procedures that involve the manipulation, retrieval and transfer of gametes and embryos. These procedures include oocyte retrieval, short term oocyte maintenance and transfer of fertilized embryos during implantation.

Technological Characteristics:

Mature oocytes may be retrieved from the patient by flushing the patient's reproductive system with PBS 1X. The oocytes may then be maintained for short periods of time in PBS 1X prior to assisted reproductive technology procedures, such as in vitro fertilization and ICSI. After fertilization, the embryo is then transferred to an appropriate culture and support medium for development in vitro. Once the desired stage of development has been achieved, usually three days post fertilization, the embryo is placed into fresh PBS 1X and transferred to the patient's uterus for implantation and development.

Performance Data:

PBS 1X is assayed by mouse embryo assay prior to its 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. PBS 1X 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 one of the standard media used for the retrieval, maintenance and transport of human gametes and embryos.

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 review of the historical information contained in professional literature shows that PBS 1X is suitable for its intended use, and meets 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

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

Re: K991342
PBS 1X, Dulbecco's Buffered Saline Solution
Dated: April 16, 1999
Received: April 19, 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: K991342

Device Name: PBS 1X

Indications for Use:

Dulbecco's Phosphate Buffered Saline Solution (PBS 1X) is intended for use in assisted reproductive technology procedures that involve the manipulation of gametes or embryos. Specifically, PBS 1X 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.

(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 K991342

Prescription Use ✓
(Per 21 CFR 801.109)