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Irvine Scientific

K991341

April 13, 1999

IRVINE SCIENTIFIC

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

Submitted by:

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Contact: Roberta L. Johnson

Date Submitted: April 13, 1999

Device Identification:

Trade Name:	ISolate® ISolate® Concentrate ISolate® Stock Solution
Common Name:	Sperm Separation Medium
Classification Name:	Cervical Cap (21 CFR, 844.5250)

Predicate Device:

ISolate® 2-layer kit	K971809

Description:

The products are a colloidal suspension of silica particles that have been covalently modified with hydrophilic silane. The colloid is formulated in a buffered physiological solution, compatible with human sperm. They are identical to the predicate device, in formulation and differ only in the intended use..

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Intended Use:

The product is intended for use in the preparation, concentration and purification of human sperm prior to assisted reproductive technology procedures, included in vitro fertilization.

Technological Characteristics:

Sperm separation media are commonly used to separate motile sperm from the other constituents of semen (such as non-viable sperm, other cell types, soluble biochemicals and proteins). The resulting concentrated and purified sperm contains more active, viable cells which may then be used in a variety of insemination procedures.

The predicate device, ISolate 2-layer kits, is a two density gradient system designed to assist in the separation of human sperm from seminal fluid. Seminal fluid is layered over the step gradient, briefly centrifuged, and the suspended pellet extracted. Due to the higher density of the motile sperm, they penetrate the density gradient to form the pellet under centrifugation, while cellular debris, and other constituents of semen, are trapped in the upper layer of the gradient. The supernatant is then remove, the pellet resuspended in an appropriate medium, and the pellet washed twice by additional centrifugation.

ISolate Concentrate and ISolate Stock Solution differ only from each other, and from the predicate, in the concentration of the colloidal silica in the formulation. ISolate Stock Solution, is, in fact, identical to the "lower layer" component of the two layer kits. They are provided for those laboratories that wish to use either a two-layer gradient with densities of their own choice, or a single gradient procedure. ISolate Concentrate is designed for further dilution by the user, into an appropriate density gradient. ISolate Stock Solution may be used as supplied, for those laboratories who choose to use a single density procedure, or may be diluted to densities of the laboratory's choice.

The intent of this submission is to expand the intended use of these devices to include sperm processing procedures prior to in vitro fertilization.

Performance Data:

ISolate Concentrate has been compared clinically to ISolate 2-layer kits, and has been found to perform comparably in sperm survival, forward progression and percent recovery of motile sperm. ISolate 2-layer kits were cleared for marketing under K971809. ISolate Stock Solution is identical to the "Lower Layer" component of the 2-layer kits.

Additional Information:

The shelf-life and biocompatibility of both ISolate Concentrate and ISolate Stock Solution are identical to the predicate device, ISolate 2-layer kits. Mouse embryo testing will not be performed on the device, but sperm survival tests are performed as a condition of release. Endotoxin and sterility tests are also performed and documented on the labeling and certificate of analysis.

Conclusion:

The conclusion from performance testing, as well as an examination of the formulations of ISolate Concentrate and ISolate Stock Solution, when compared to the predicate, ISolate 2-layer kits, shows that the devices are substantially equivalent for the preparation and concentration of human sperm prior to use in insemination procedures in assisted reproductive technology, including in vitro fertilization.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K991341
ISolate®; ISolate® Concentrate; ISolate® Stock 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: K991341

Device Name: ISolate®; ISolate® Concentrate; ISolate® Stock Solution

Indications for Use:

ISolate® is a density gradient medium designed to separate the motile fraction of sperm from seminal fluid. As a two-layer gradient system, it effectively reduces cellular contaminants such as dead sperm, white blood cells and miscellaneous debris. The resulting sample contains predominantly motile sperm. It is intended for use as a human sperm separation medium, to concentrate and purify viable sperm, prior to in vitro fertilization, and related 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)

Prescription Use ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K991341