DEC 2 6 2002

510(k) SUMMARY

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K023222.

Submitted by: InVitroCare, Inc.
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Contact: Robert E. Lovins, PhD
Date Submitted: September 27,2002

Device Identification:

Trade Name: ISOCARE ONE-STEP Sperm Processing Medium

Common Name: Sperm isolation and processing medium, Human Tubal Fluid medium

Classification Name: Reproductive Media (21CFR, 886.6180)

Predicate Device:

Notice of Final Rule, 63 FR 48428, Docket number 97N-0335 and 510(k) Reference Number K983588

Description:

ISOCARE ONE-STEP Sperm Processing Medium is a synthetic, defined culture medium composed of a mixture of salts and other physiologically compatible substances supplemented with 5mg/ml human serum albumin. ISOCARE ONE-STEP Sperm Processing Medium is intended for use in sperm processing procedures prior to intrauterine or other assisted reproductive technology procedures. It has been formulated to mimic the composition of the fluid found in fallopian tubes as defined by Quinn etal (Quinn P, Kerin JF, Warnes GM: Fertil Steril 1985;44:493-498). ISOCARE ONE-STEP Medium uses a combined sodium bicarbonate/HEPES ([4-(2-hydroxyethyl)-1-piperazineethanesulfonic acid]) buffering system and is appropriate for those procedures that do not use a carbon dioxide atmosphere.

Intended Use:

ISOCARE ONE-STEP Sperm Processing Medium is intended for use in assisted reproductive technology procedures that involve the isolation, processing and transfer of sperm. Specifically, ISOCARE ONE-STEP Sperm Processing Medium is intended for use as a sperm isolation and processing medium in the isolation and processing of sperm during intrauterine and other reproductive technology procedures.

Design Characteristics:

ISOCARE ONE-STEP Sperm Processing Medium is intended for use as a culture medium for a variety of assisted reproductive procedures. During sperm isolation and processing procedures, sperm cells are separated from the other constituents of seminal fluid in an effort to concentrate the viable sperm and increase the number of sperm available for fertilization. A culture medium such as ISOCARE ONE-STEP Sperm Processing Medium is used to suspend the semen, the sample is centrifuged, and, after the spent semen layer is decanted, the lower ISOCARE Layer, containing the concentrated sperm sample can be used directly for intrauterine insemination. Alternatively, the sperm containing ISOCARE layer can be diluted with sperm wash medium and centrifuged to obtain a purified sperm pellet which may be used used for the desired fertilization procedure. ISOCARE ONE-STEP Medium is therefore intended for use as a sperm isolation and processing medium in assisted reproductive technology procedures.

Performance Data:

ISOCARE ONE-STEP Sperm Processing Medium is subjected to cytotoxicity testing and sperm motility/hyperactivation analysis. Each lot of ISOCARE ONE-STEP Medium is also assayed by a mouse embryo assay prior to its release to market. These assays assure that the product is both functional for its intended use, and that no toxic components are present in the formulation. Sperm isolation and processing media have been used in a variety of clinical settings, for the intended use for a number of years. In that time the product has become the standard media used for sperm isolation, washing and transport.

Additional Information:

Mouse embryo testing will be performed as a condition of release for ISOCARE ONE-STEP Sperm Processing Medium as well as endotoxin and sterility testing. Results of all release assays 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 published historical information contained in the professional literature shows that ISOCARE ONE-STEP Sperm Processing Medium is suitable for its intended use and meets the criteria outlined in the Final Rule, 63 FR48428, Docket number 97N-0335.

PROPOSED LABELING

Three copies of the proposed labeling for ISOCARE ONE-STEP Sperm Processing Medium are enclosed with is submission, beginning on the following page. These labels include vial and box labels, and proposed product brochure. 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 certificate of analysis, and the information supplied in them may be found in labeling section of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 26 2002

Robert E. Lovins, Ph.D.
President,
InVitroCare, Inc.
11760-H Sorrento Valley Rd.
SAN DIEGO CA 92121

Re: K023222
Trade/Device Name: ISOCARE ONE-STEP Sperm Processing Medium
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: December 3, 2002
Received: December 5, 2002

Dear Dr. Lovins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, 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: K023222

Device Names: ISOCARE ONE-STEP Sperm Processing Medium

Indications for Use:

ISOCARE ONE-STEP Sperm Processing Medium is intended for use in assisted reproductive technology procedures that involve the isolation, processing and transfer of sperm. Specifically, ISOCARE ONE-STEP Sperm Processing Medium is intended for use as a sperm isolation and processing medium in the isolation and processing of sperm during intrauterine and reproductive technology procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K023222

Prescription Use ✓
(per 21 CFR 801.109)