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JUL 3 1997

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Contact: Dr. Ken Lydersen

Date: May 12, 1997

Device Identification:

- Trade Name: ISolate
- Common Name: Sperm Separation Medium
- Classification Name: Cervical Cap (per 21CFR 884.5250)

Predicate Devices:

- Sperm Select (K872849)
- Modified Ham's F-10 (K894432)

Description:

The product is a colloidal suspension of silica particles which have been covalently modified with hydrophilic silane. The colloid is formulated in a buffered physiological solution compatible with human sperm. The product is packaged in two formats. One format consists of a kit of two solutions which differ only in the concentration of the colloidal silica, and therefore in their density. The two solutions, labeled "Upper" and "Lower", are utilized to form a step-gradient in a centrifuge tube. The other product format is a single solution which can be utilized as a "stock solution" to create a different step gradient from that provided by the kit. This latter solution is identical to the "Lower" (i.e., higher density) solution.

Intended Use:

The product is intended for use in the preparation of human sperm for intrauterine insemination (IUI).

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Technological Characteristics:

Sperm separation media are used to separate motile sperm from the other constituents of semen (i.e., non-viable sperm, other cell types, soluble biochemicals and proteins). Centrifugation is the technology most commonly used to separate sperm from the soluble components of semen. Centrifugation followed by aspiration of the supernatant and resuspension of the pellet in a medium such as Modified Ham's F-10 is the most straightforward method of sperm preparation, resulting in a "washed" sperm preparation. If separation of motile sperm from other cellular constituents is desired, the pellet is incubated under a layer of medium (i.e., Modified Ham's F-10) instead of being resuspended. The motile sperm "swim-up" into the fresh medium, resulting in a sperm preparation with an increased % motility, but a decreased recovery.

The centrifugation of semen in a medium with high density is an approach which can separate motile, viable sperm from other cellular constituents without the reliance on "swim-up". This method has been used extensively with a colloidal silica product (Percoll) formulated with a variety of physiological buffers. Isolate utilizes a similar colloidal silica product to accomplish sperm separation.

Another approach is to utilize a medium with a high viscosity. If a highly viscous solution is layered over a semen sample and incubated for a sufficient length of time, motile sperm, but not other cells, will migrate into the viscous solution and allow the recovery of a fraction of the original sperm containing a high proportion of motile sperm.

Although the centrifugation of viable sperm through a high density medium is commonly used, there are no devices approved for sperm separation utilizing this technology. Modified Ham's F-10 (K894432) is a predicate device approved for sperm preparation utilizing centrifugation and washing or "swim-up". Sperm Select (K872849) is another predicate device which utilizes high viscosity medium. For the purposes of this application, ISolate has been compared to Modified Ham's F-10, as used in Washing and Swim-Up, and Sperm-Select.

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Performance Data:

Semen samples (fresh and cryopreserved) were processed in parallel using ISolate and the predicate devices, as well as Percoll in some cases. The resulting purified sperm preparations were assayed for recovery, motility, viability, forward progression and normal forms. The results showed that sperm prepared with ISolate resulted in preparations which were substantially equivalent to those from the predicate devices.

Conclusion:

The conclusion from the performance testing and the biocompatibility testing is that ISolate yields substantially equivalent results to the predicate devices in the preparation of human sperm for intra-uterine insemination (IUI).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Rockville MD 20850

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JUL - 3 1997

Re: K971809
ISolate Sperm Separation Media
Dated: May 12, 1997
Received: May 15, 1997
Regulatory class: unclassified
Product code: 85 MQL

Dear Dr. Lydersen:

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 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 requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971809

Device Name: ISolate

Indications For Use: This product is intended for use as a human sperm separation medium for intra-uterine insemination (IUI).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Sattler
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971809

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

SK-36