K061145

510(k) Summary

OCT - 2 2006

Submitted by: MediCult a/s
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Contact person: Ronald G. Leonardi, Ph.D.
R&R Registrations
9919 Cam. Chirimolla
San Diego CA 92131

Date Submitted: September 6, 2006

Device Identification:
Trade name: SpermSlow™
Common name: SpermSlow™
Classification name: Reproductive media and supplements (21 CFR 884.6180, Product Code MQL)

Predicated device:
MediCult PVP Medium (K991329).

Description
SpermSlow™ is a defined medium used by professionals within assisted reproduction designed to slow down the movement and to select the most mature, viable sperm as required for Intracytoplasmatic sperm injection (ICSI). SpermSlow™ is principally composed of hyaluronate (HA), the main component of the extracellular matrix, which appears in large amounts between the cumulus cells of the matured oocyte-cumulus complex.
SpermSlow™ is based on a sodium bicarbonate buffered solution containing hyaluronate, HSA (US licensed source), pyruvate, glucose, amino acids, nucleotides, vitamins and antibiotics.
SpermSlow™ is supplied in polypropylene plastic vials with screw top closures in a volume of 0.5ML. Each unit is labelled and the product is presented in four pack containers which also include a package insert.

Intended use
SpermSlow™ is used to slow down the movement of sperm to allow for the selection of the most mature, viable sperm for Intracytoplasmic sperm injection (ICSI).

Technological Characteristics
The technological characteristics of SpermSlow™ are essentially similar to those of the predicate device; it has the same intended use and is based on a physiological salt solution. However, SpermSlow™ differs in the composition in also containing vitamins, amino acids, nucleotides and hyaluronate instead of polyvinylpyrrolidone.

Performance data
SpermSlow™ has been tested in a human study. The results show that the product is effective for its intended use.
It has been marketed in Europe since May 2004 and there has been no evidence of any serious adverse events in connection with the intended use.

Product Testing Controls
Each batch of SpermSlow™ is tested according to Ph.Eur and USP for sterility and endotoxin and each batch is also tested for viscosity and sperm survival. The results are reported on a certificate of analysis. Stability studies have been performed.

Conclusion
Thus based on the performance testing presented and our experience with the SpermSlow product, we feel that the safety and the effectiveness of the product for its intended use are shown in the present submission and that the product is substantial equivalent to the predicated device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

OCT - 2 2006

MediCult a/s
c/o Ronald G. Leonardi, Ph.D.
President
R&R Registrations
9915 Cam. Chirimolla
SAN DIEGO CA 92131

Re: K061145
Trade/Device Name: SpermSlow™
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: September 27, 2006
Received: September 28, 2006

Dear Dr. Leonardi:

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 (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 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 Section 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:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

510(k) Number (if known): K061145

Device Name:

SpermSlow™

Indications For Use:

SpermSlow™ is used to slow down the movement of sperm to allow for the selection of the most mature, viable sperm for Intracytoplasmic sperm injection (ICSI).

Prescription Use __x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(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,
and Radiological Devices
510(k) Number K061145