510(k) summary

K060983

Submitted by: MediCult a/s
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Contact person: Ronald G. Leonardi, Ph.D.

JUL 28 2006

Date Submitted: June 15. 2006

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

Predicate device:
Embryo Biopsy Medium from Irvine Scientific (K021358) and the Sydney IVF Embryo Biopsy Medium from Cook (K023850).

Description
MediCult Biopsy Medium is a defined sterile media used by professionals within assisted reproduction and designed for blastomere biopsy of cleavage stage embryos for pre-implantation genetic diagnosis (PGD). The formulation is based on a HEPES-buffered HTF solution added SSR (Synthetic Serum Replacement; ART supplement), human serum albumin (HSA) and amino acid but without calcium and magnesium ions to facilitate the process of biopsy. The absence of calcium and magnesium ions reversibly reduces the cellular connection between the blastomeres making it easy to excise a blastomere from the embryo without fatal trauma.
Biopsy Medium is supplied in 10 ml polyethylene plastic vials with screw top closures.

Intended use
Biopsy Medium is intended for blastomere biopsy of cleavage stage embryos for PGD (pre-implantation genetic diagnosis)

Technological Characteristics
The technological characteristics of Biopsy Medium are essentially similar to those of the predicate devices they have the same intended use and are based on a physiological salt solution with amino acids and like the predicate devices without calcium and magnesium. However, Biopsy Medium differs in the composition in containing SSR. This change does not affect the safety or effectiveness of the device.

Performance data
Biopsy Medium has been tested in a human study. The results showed that the product is effective for its intended use.
If has been marketed in Europe since 2002 and there has been no registered complaints and no evidence of any serious adverse events in connection with the intended use.

Product Testing Controls
Biopsy Medium has been cytotoxicity tested. Each batch is tested according to Ph. Eur. and USP for sterility, osmolality, pH, endotoxin and MEA. 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 Biopsy Medium product, we feel that the safety and the effectiveness of the product for its intended use is shown in the present submission and that the product is substantial equivalence to the predicated device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 2 8 2006

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

Re: K060983
Trade/Device Name: Biopsy Medium
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: July 10, 2006
Received: July 11, 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) K060983

Device Name: Biopsy Medium

Indications for Use:

Biopsy Medium is indicated for blastomere biopsy of cleavage stage embryos for PGD (pre-implantation genetic diagnosis)

(PLEASE DO NO WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-The-Counter Use** ___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K060983