MAY - 9 2000

510(k) Summary
Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination
(K991471)

The product:

- **"Medi-Cult Blastocyst Freezing Pack" Cat.No. 1012**
- **"Medi-Cult Blastocyst Thawing Pack" Cat.No. 1015**

Indication for use:
"Medi-Cult Blastocyst Freezing Pack" is for freezing of blastocysts in a two step procedure and the "Medi-Cult Blastocyst Thawing Pack" is for thawing of blastocysts in a two step procedure.

Products formulation:
"Medi-Cult M3 Medium" has been used as the basal medium for both products. Furthermore Blastocyst Freezing Pack contains glycerol (vial 1) and glycerol and Sucrose (vial 2). Blastocyst Thawing pack contains sucrose (vial 1 and 2).

Product testing control contents:
- **Bioburden, production-test**
- **Integrity filter testing, production-test**
- **Sterility, QC-test**
- **pH, QC-test**
- **Mouse Embryo, QC-test (Two cell assay; $\geq$ 80% hatched) QC Test**
- **Endotoxin, QC-test**

Medi-Cult has recently introduced a product intended for cryopreservation and thawing of human blastocyst. This product is based on the work of Yves Menezo and co workers who have developed a protocol for freezing and thawing of human blastocysts. (Yves Menezo et al: In Proceedings of ASRM, Boston, USA, 1996, P006 and Yves Menezo and Anna Veiga: In proceedings of the 10th World Congress of In Vitro Fertilization and Assisted Reproduction, Vancouver (Canada), May 24-28, 1997, pp. 49-53.)

Since our introduction of a commercially available product identical to the formulation of Menezo and co-workers, many clinics have started to use The Medi-Cult Blastocyst Freezing and Thawing pack. The first clinical data available indicates that this product has the same performance as indicated by Menezo et al.

Thus based on the Federal Register Notice (Final Rule, Vol. 63, No. 175, page 48429, September 10, 1998), "Obstetric and Gynecologic Devices; Reclassification and Classification of Medical Devices Used for In-Vitro Fertilization and Related Assisted Reproduction Procedures" effective on October 13, 1998 and the supportive clinical data we feel that the safety and effectiveness of the product for its intended use is shown in the present submission.

Prepared and Submitted by:

Reena Wimberg-Leonardi for February 16, 2000

Ronald G. Leonardi, Ph. D. **Date**
President
R & R Registrations
P.O. Box 262069
San Diego CA 92196
1-619-586-0751

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 9 2000

Medi-Cult A/S
c/o Ronald G. Leonardi, Ph.D.
R & R Registrations
P.O. Box 262069
San Diego, CA 92196-2069

Re: K991471
Medi-Cult Blastocyst Freezing and Thawing Packs
Catalog #1012 and 1015
Dated: April 3, 2000
Received: April 4, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Dr. Leonardi:

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) 594-4591. 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" (21CFR 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,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510(k) Number (if known) **K991471**

Device Name: **Medi-Cult Blastocyst Freezing Pack and Medi-Cult Blastocyst Thawing Pack**

Indications for Use:

Blastocyst Freezing pack is for freezing of blastocysts in a two-step procedure.

Blastocyst Thawing pack is for thawing of blastocysts in a two-step procedure.

(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, ENT,
and Radiological Devices
510(k) Number K991471