JUN 2 7 2003

K031486

510(k) Summary

Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination

The Products
BlastFreeze™ and BlastThaw™, Cat.No. 10532010 and 10542010

Indications for use:
For freezing and thawing human blastocysts.

Composition:
BlastFreeze and BlastThaw are based on Earle's Balanced Salts Solution and differing concentrations of sucrose. BlastFreeze contains glycerol as the cryprotectant.

Stability and biocompatibility testing
BlastFreeze and BlastThaw have been stability tested. When following the procedure described in our package inserts BlastFreeze and BlastThaw will not be patient contacting that is why biocompatibility testing has not been performed.

Product testing controls
1. Sterility
2. pH
3. Endotoxin tested ≤ 0.1 EU/ml (USP)
4. Mouse Embryo Assay, (two-cell assay, blastocyst rate μ 80 %)

For each batch a Certificate of Analysis with the results of the above tests is available.

Clinical Documentation:
The clinical documention show a survival rate of around 80% and an implantation rate of 15% after freezing and thawing of human blastocysts. No difference in results between IVF and ICSI.
The abortion rate is low, being 14 % in IVF patients and 0 in ICSI patients.

BlastFreeze and BlastThaw products have demonstrated their suitability in daily clinical practice for freezing and thawing of blastocysts giving survival and implantation rates similar to the results obtained by using other products available for freezing and thawing blastocysts (Ménézo.Y and Veiga.A, 1997). In addition, by using BlastFreeze and BlastThaw the abortion rate can be lowered.

BlastFreeze and BlastThaw were marketed in Europe in April 2002. There has been no registered complaints and no evidence that the product has been the cause of any serious adverse events in connection with its intended use.

Based on the clinical data presented and our experience with the BlastFreeze and BlastThaw products we feel that the safety and effectiveness of the product for its intended use is shown in the present submission and the products are substantially equivalent to the predicated devices, our Blastocyst Freezing Pack and Blastocyst Thawing Pack (K 991471)

Prepared and Submitted by:

May 9, 2003

Ronald G. Leonardi, Ph.D.
President
R & R REGISTRATIONS
P.O. Box 262069 San Diego, Ca 92131
858-586-0751

Date

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 2003

Medi-Cult a/s
% Ronald G. Leonardi, Ph.D.
President
R & R Registrations
P.O. Box 262069
SAN DIEGO CA 92196-2069

Re: K031486
Trade/Device Name: BlastFreeze™ and BlastThaw™
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: May 9, 2003
Received: May 14, 2003

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 (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 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 the 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" (21CFR Part 807.97) you may obtain. 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

510(k) Number (if known) K031486

Device Name: **BlastFreeze™** and **BlastThaw™**

INDICATIONS FOR USE:

BlastFreeze™:
For freezing of human blastocysts.

BlastThaw™:
For thawing of human blastocysts.

(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 K031486