JUN 2 0 2000

510(k) Summary
Summary of Safety and Effectiveness Information Supporting a Substantially Equivalent Determination
(K991331)

The products:

- "Medi-Cult M3 Medium" Cat.No. 1033
- "Medi-Cult M3 Medium w/o Pen/Strep." Cat.No. 1032
- "Medi-Cult M3 Medium w/o Phenol Red" Cat.No. 1037

Indication of use:
"Medi-Cult M3 Medium" is intended for the culture of embryos from day 3 and up to day 7.
Product formulation:
"Medi-Cult M3 Medium" is based on MCDB 302; a modification of HAM's F10 and F12 composed of amino acids, vitamins, inorganic salts and glucose supplemented with:

Assisted Reproduction Technique Supplement (ARTS)
Sodium Bicarbonate
Human Serum Albumin (HSA) (obtained from a licensed source, U.S. license No. 140)
Penicillin (Except product 1032)
Streptomycin (Except product 1032)
Phenol Red (Except product 1037)

Products testing control contents:
- Bioburden, production-test
- Integrity filter testing, production-test
- Sterility, QC-test
- pH, QC-test
- Osmolarity, QC-test
- Endotoxin, QC-test

The culture media from Medi-Cult have been used by many European IVF-units since the end of the 1980's. (Produced and distributed by GEA-Biotech 1987 to 1989 and by Medi-Cult a/s from 1989)

The Medi-Cult M3 medium was introduced in 1992 to allow extended culture of embryos beyond day 2/3 after fertilisation. The Medi-Cult M3 medium has been used by several clinics obtaining good morula/blastocyst formation and good pregnancy rates.

A few prospective randomised studies have been performed showing that the Medi-Cult M3 medium performs equally well as other products available for extended culture.

One center performed a prospective randomised study comparing the Medi-Cult M3 medium with the Scandinavian Science S2 medium. They found a similar rate of blastocyst formation (Source Dr. Anita Sjögren the Dept of Ob. & Gyn., Sahlgrenska hospital in Gothenburg, Sweden, data presented as poster at The world IVF meeting in Boston 1995).

The Jones Institute for Reproductive Medicine, Eastern Virginia Medical school, Norfolk, USA, has performed a prospective randomised study comparing the rate of blastocyst formation when human embryos are cultured in two different commercially available culture systems. The embryos were cultured either in the Medi-Cult universal IVF-medium for 2 days followed by The Medi-Cult M3 or in S1 for 2 days followed by S2 from Scandinavian IVF Science. The rate of blastocyst formation was similar in both groups (26% vs 27% respectively).

There have been no registered complaints on the product and there is no evidence in the last 1.5 year that the product has been the cause of any serious adverse events in connection with its intended use.

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:

Ronald G. Leonardi, Ph. D. Date

President
R & R Registrations
P.O. Box 262069
San Diego CA 92196
1-858-586-0751

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 0 2000

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

Re: K991331
Medi-Cult M3 Medium
Dated: May 22, 2000
Received: May 23, 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) K991331

Device Name: Medi-Cult M3 Medium

Indications for Use:

M3 Medium is used for the culture of embryos from day 3 and up to day 7.

(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 K991331