JUL 2 0 2000

510(k) Summary
Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination
(K991279)

The products:

- "Medi-Cult Universal IVF Medium" Cat.No. 1031
- "Medi-Cult Universal IVF Medium w/o Phenol" Cat.No. 1030
- "Medi-Cult Universal IVF Medium w/o Pen/Strep" Cat.No. 1095

Indications for use:
"Medi-Cult Universal IVF Medium" is for fertilisation of human oocytes and culture of fertilised oocytes up to the 4-6-cell stage (day 2 after insemination). "Medi-Cult Universal IVF Medium" can also be used as vehicle during embryo transfer.

Product formulation:
Earl's Balanced Salt Solution (EBSS)
Sodium Pyruvate
Assisted Reproduction Technology Supplement (ARTS)
Sodium Bicarbonate
Human Serum Albumin (HSA)
Penicillin (Except product 1095)
Streptomycin (Except product 1095)
Phenol Red (Except product 1030)

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

The culture media from Medi-Cult have been used by many European IVF-units since the end of 1980. (Produced and distributed by GEA-Biotech 1987 to 1989 and by Medi-Cult a/s from 1989). The Medi-Cult media were at that time introduced as a replacement for in-house prepared culture media.

A number of prospective randomized trials have shown that The Medi-Cult-IVF-medium performs equally well or better than alternative culture media. A number of publications in peer-reviewed books or journals have presented data using Medi-Cult media.

The clinical result of a given IVF-clinic will depend on the patient population treated, the clinical procedures, laboratory routines and on the various culture media used. A comparison of the clinical performance of clinics using only Medi-Cult media with other IVF-clinics using similar clinical and laboratory routines will give an indication on the performance of the Medi-Cult culture media. In countries where we have access to both national data and data from individual clinics, clinics using Medi-Cult media generally perform well.

The IVF-units in the Nordic countries use similar clinical and laboratory protocols and their patient populations are comparable. The clinical data from most Nordic countries are available. In some countries the performance of individual IVF-clinics are available.

The largest IVF clinics in Norway have been using only Medi-Cult media since the end of the 1980's. The data collected in the years from 1992 to 1996 are shown below as live birth rates per started cycle.

Table 1. Live birth rates per started cycle obtained in IVF units in Norway

Clinic	1992	1993	1994	1995	1996
Dept of Ob & Gyn, Univ of Trondheim	22.2	22.2	19.8	25.35	18.4
The National Hospital, Oslo	13.3	19.0	15.8	11.42	17.4
National average	14.6	17.5	17.9	16.84	16.3

In Sweden, the Carl von Linne Clinic uses only products from Medi-Cult for culture of gametes and embryos. For the year 1997 their birth rate per embryo replacement was 34% their clinical results were the best in Sweden and well above the national average of 25.8%.

The Human Fertilization and Embryology Authority (HFEA) in the UK collects clinical data from all centers licensed to offer treatment for infertility by assisted reproduction. HFEA publishes these data in a booklet and on the web. The clinical data are presented both unadjusted and adjusted for the demographics of the clinics patient population.

In the Table below the clinical data from some UK-clinics that use only Medi-Cult products is shown. These clinics have all given their consent to be presented as clinics using only Medi-Cult products.

Table 2. Live birth rates per embryo replacement obtained in IVF units in the UK in the period April 1st 1996 to March 31, 1997.

Name of clinic	Number of IVF- cycles	Live birth rate per embryo replacement %
Northamptonshire Fertility service	503	26.0
The Bridge Centre	852	27.2
Chelsea and Westminster Hospital	388	22.3
CARE at Park Hospital	650	34.5
BMI Ross Hall Hospital	68	27.5
The Woking Nuffield Hospital	163	32.6
Leeds General Infirmary	1434	24.0
Nurture	1245	28.8
Holly House Fertility and IVF	333	30.5
Guy's and St Thomas Assisted Conception Unit	651	27.1
UK national average	33520	21.8

There have been some registered complaints on the product but there is no evidence in the last 1.5 years 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:

Rene Wiehe-Leonardi for 4/22/00

Ronald G. Leonardi, Ph. D. Date
President
R & R Registrations
P.O. Box 262069 San Diego CA 92196
858-586-0751

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 2 0 2000

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

Re: K991279
Medi-Cult Universal IVF-Medium-Assisted
Reproduction Technology Supplement (ARTS)
Dated: April 20, 2000
Received: April 21, 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): K991279

Device Name: **Medi-Cult Universal IVF Medium**

Indications for Use:

Medi-Cult Universal IVF Medium is used for the fertilization of human oocytes and culture of fertilized oocytes up to the 4-6-cell stage (day 2 after insemination).

Medi-Cult Universal IVF Medium can also be used as vehicle during embryo transfer.

(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)

David A. Gross

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991279