K991329

B5. 510(k) Summary

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

The media "Medi-Cult PVP Medium" for support of In-Vitro fertilisation has been used extensively over a number of years to the satisfaction of the users at the IVF- and ART- clinics and laboratories.

There have been some registered complaints on the product, but 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.

A number of trials have shown that the Medi-Cult PVP Medium and other products performs well. (see Clinical Testing section reference list). A number of publications in peer- reviewed books or journals have presented data using Medi-Cult media. Often more than one product from Medi-Cult has been used in the studies listed.

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:

4/16/99

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

FEB 25 2000

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

Re: K991329
Medi-Cult PVP, Medium and
Medi-Cult PVP, Clinical Grade
Dated: November 30, 1999
Received: December 1, 1999
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
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

B4. Indication for Use Statement

510(k) Number (if know) K991329

Device Name: **Medi-Cult PVP Medium**

Indications for use:

Medi-Cult PVP products are used for decreasing the motility and movements of sperm before ICSI.

PLEASE DO NOT 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 K991329