

**MAR - 7 2000**

**Medi=Cult**

**510(k) Summary  
Summary of Safety and Effectiveness Information  
Supporting a Substantially Equivalent Determination  
(K991470)**

**The product:**

- **"Medi-Cult Acidified Tyrodes Solution" Cat.No. 1060**

**Indications for use:**

**For drilling of the zona pellucida.**

**("Medi-Cult Acidified Tyrodes Solution" has for many years been used to chemically etch (drill) holes in the zona pellucida. The low pH of the solution will dissolve the polymers constituting the zona pellucida).**

**Product formulation:**

- **Potassium Chloride**
- **Calcium Chloride**
- **Magnesium Chloride**
- **Sodium Phosphate Monobasic**
- **Glucose**
- **Povidone K-90, polyvinylpyrrolidone**
- **Sodium Chloride**

**Product testing control contents:**

- **Bioburden, production-test**
- **Integrity filter testing, production-test**
- **Sterility, QC-test**
- **pH, QC-test**

**The culture media from Medi-Cult have been used by many European IVF-units since the end of the 1980'ties. (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.**

**Zona drilling has been performed to facilitate hatching (assisted hatching). Acidified Tyrodes solution has been routinely used for chemically etching a whole (drilling) in the zona pellucida. Medi-Cult produces an acidified Tyrodes solution based on published data. The product has been designed especially for IVF procedures for zona pellucida perforation. Acidified Tyrodes Solution is a ready-to-use product with a pH between 2.3 and 2.5 for zona perforation.**

**Revised 3/1/2000**

**K991470**

**2/16/2000**

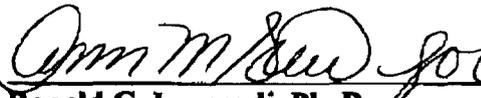
## Medi≡Cult

The initial clinical testing of Medi-Cult acidified Tyrodes has been done by Dr. Alan Handyside, Dept. Of Obstetrics and Gynecology, St. Thomas' Hospital, Londn, UK and by Søren Ziebe, the National Hospital, Copenhagen, Denmarke (Søren Ziebe, Anders Nyboe Andersen, Anne-Grethe Andersen, Anne Lis Mikkelsen and Svend Lindenberg. Results of intracytoplasmic sperm injection in relation to indication Acta Obstetricia et Gynecologica Scandinavica 1997; 335-339.)

There have been no registered compliants on the product and 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 1 , 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 products for its intended use is shown in the present submission.

Prepared and Submitted by:

 for March 1, 2000  
Date

Ronald G. Leonardi, Ph. D.

President

R & R Registrations

P.O. Box 262069

San Diego CA 92196

858-586-0751



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Medi-Cult A/S  
c/o Ronald G. Leonardi, Ph.D.  
President  
R & R Registrations  
9915 Cam. Chirimolla  
San Diego, CA 92131

Re: K991470  
Medi-Cult Acidified Tyrodes Solution - Medium  
Dated: February 18, 2000  
Received: February 22, 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)

