MAY 10

K060699

510(K) SUMMARY

Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

SynVitro®Cumulase™ is a sterile non preserved solution containing 80 U/mL of recombinant human enzyme hyaluronidase (rHuPH20) in a HEPES buffered salt solution with SSR (Synthetic serum replacement) added.

Intended Use
SynVitro®Cumulase™ is used by professionals within assisted reproduction for the removal of the cell complex (cumulus and corona radiata) surrounding the oocyte in the preparation for intracytoplasmatic sperm injection (ICSI).

Biocompatibility testing
The product is not in contact with the patient, thus, biocompatibility studies have not been performed.

Product Testing Controls
SynVitro®Cumulase™ has been cytotoxicity tested. Each batch is tested according to Ph. Eur. and USP for sterility, osmolality, pH and cytotoxicity using the Mouse embryo Assay (MEA). Stability studies have been performed.

Clinical Documentation
The predicated device is MediCult's SynVitro®Hyadase (K031228). The efficiency of removing the cumulus from the oocytes have been compared to the predicated device in a prospective, randomised clinical study .The study showed that the two products were equally effective for removal of cumulus cells prior to ICSI.

There has been no registered complaints and no evidence of any serious adverse events in connection with the intended use, during these studies.

It is concluded that SynVitro™Cumulase is substantially equivalent to the predicated device SynVitro®Hyadase.

Prepared and Submitted for MediCult by:

March 14, 2006

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

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

MAY 10 2006

MediCult a/s
% Ronald G. Leonardi, Ph.D.
President
R&R Registrations
9915 Cam. Chirimolla
SAN DIEGO CA 92131

Re: K060699
Trade/Device Name: SynVitro® Cumulase™
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: March 14, 2006
Received: March 17, 2006

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

Indications for Use

K060699

510(k) Number (if known): K060699

Device Name:

SynVitro®Cumulase™

Indications For Use:

SynVitro®Cumulase™ is indicated for the removal of the cell complex (cumulus and corona radiate) surrounding the oocyte in preparation for the ICSI procedure.

Prescription Use ___x__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
Page 1 of _____

Nancy C. Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060699