K080473

SEP - 3 2008

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

Submitted by: MediCult a/s
Møllehaven 12
4040 Jyllinge
Denmark
Telephone: + 45 46 79 02 00
Fax: + 45 46 79 03 00

Contact person: Ronald G. Leonardi, Ph.D.
R&R Registrations
9919 Cam. Chirimolla
San Diego CA 92131

Date Submitted: 2008, August

Device Identification
Trade name: EmbryoAssist™ and EmbryoAssist™ with Phenol Red
Common name: EmbryoAssist™ and EmbryoAssist™ with Phenol Red
Classification name: Reproductive media and supplements (21 CFR 884.6180, Product Code MQL)

Predicate device:
Universal IVF Medium (K991279), EmbryoAssist™ (K061309) and ISM1™ (K030490) from MediCult.

Description
EmbryoAssist™ and EmbryoAssist™ with Phenol Red are each a defined sterile media used by professionals within assisted reproduction and intended for fertilization and culture until the 2-8 cell stage. EmbryoAssist™ and EmbryoAssist™ with Phenol Red can also be used for embryo transfer at day 2 or 3.
The composition of EmbryoAssist™ and EmbryoAssist™ with Phenol Red are almost identical to the predicate device EmbryoAssist™ (K061309), but with an extension of the intended use including a transfer indication.
The EmbryoAssist™ medium is a salt solution containing SSR (Synthetic Serum Replacement), HSA, amino acids, a stable form of L-glutamine, vitamins and antibiotics. EmbryoAssist™ is supplied in 10 ml and 60 ml polyethylene plastic vials with screw top closures.

Intended use
EmbryoAssist™ and EmbryoAssist™ with Phenol Red are for fertilization and culture until the 2-8 cell stage. EmbryoAssist™ and EmbryoAssist™ with Phenol Red can also be used for embryo transfer at day 2 or 3.

Technological Characteristics
The technological characteristics of EmbryoAssist™ are essentially similar to those of the predicate devices. They have the same intended use and are based on a physiological salt solution with SSR and amino acids.

Performance data
EmbryoAssist™ has been tested as both culture and transfer medium in a human study. The results showed that the product is effective and safe for its intended use. During our studies there have been no registered complaints and no evidence that the product has been the cause of any serious adverse events in connection with the intended use.

Product Testing Controls
Each batch is tested according to Ph. Eur. and USP for sterility, osmolality, pH, endotoxin and Mouse Embryo Assay (MEA). Stability studies have been performed.

Conclusion
It is concluded that the safety and the effectiveness of the product for its intended use is shown in the present submission and that the products are substantial equivalent to the predicate device MediCult's Universal IVF Medium (K991279), MediCult's EmbryoAssist™ (K061309)and MediCult´s ISM1™ (K030490).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

SEP - 3 2008

MediCult A/S
c/o Ronald G. Leonardi, Ph.D.
R&R Registrations
9915 Cam. Chirimolla
SAN DIEGO CA 92131

Re: K080473
Trade/Device Name: EmbryoAssist™ and EmbryoAssist™ with Phenol Red
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproduction Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: July 29, 2008
Received: July 30, 2008

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

510(k) Number (if known): K080473

Device Name:

EmbryoAssist™ with Phenol Red

Indications for Use:

EmbryoAssist™ with Phenol Red is for fertilization and culture until the 2-8 cell stage. EmbryoAssist™ with Phenol Red can also be used for embryo transfer at day 2 or 3.

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)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K080473

Indications for Use

510(k) Number (if known): K080473

Device Name:

EmbryoAssist™

Indications for Use:

EmbryoAssist™ is for fertilization and culture until the 2-8 cell stage. EmbryoAssist™ can also be used for embryo transfer at day 2 or 3.

Prescription Use __x___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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