K031228

JUN 24 2003

510(k) Summary

Summary of Safety and Effectiveness Information
Supporting a Substantially Equivalent Determination

Intended use
SynVitro® Hyadase is for the removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.

Composition
- Hyaluronidase 80 IU/ ml (non-bovine source)
- ART supplement
- Glucose
- Sodium pyruvate
- Calcium chloride
- Magnesium sulphate
- Sodium chloride
- Sodium bicarbonate
- HEPES

Biocompatibility testing
When following the procedure described in our package insert SynVitro®Hyadase will not have patient contact, thus biocompatibility testing has not been performed.

Product testing controls
Sterility tested
pH tested
Osmolality tested
Mouse Embryo Assay, (one cell assay, Blastocyst rate > 70 %)
For each batch a Certificate of Analysis with the results of the above tests is available.

Clinical Documentation:
Prior to the ICSI procedure, the cells of the cumulus and corona radiata must be removed in order to facilitate access to the oocyte and minimize contamination of the injection needle.

SynVitro® Hyadase is a ready-to-use hyaluronidase product designed for denudation of the oocyte and is based on raw material from a non-bovine source. SynVitro®Hyadase does not contain human serum albumin (HSA) or antibiotics.

Hyaluronidase originating from two different sources were compared in a clinical study. Two comparable groups of oocytes were inseminated after the cumulus had been removed using one of the two sources of hyaluronidase. The result of the study showed that there was no significant difference between the two groups regarding the morphological quality of the embryos, the fertilisation rate and the clevage rate.

Furthermore a randomised clinical study has been performed comparing SynVitro® Hyadase, which does not contain human serum albumin (HSA) to Medi-Cult's Hyaluronidase product that contains HSA. The results of this study is that SynVitro® Hyadase and Medi-Cult Hyaluronidase are equally effective regarding the morphological quality of the embryos, the fertilisation rate and the cleavage rate.

Based on these studies it is concluded that SynVitro® Hyadase is substantial equivalent to Medi-Cult Hyaluronidase (K 991334) and is effective for denuding oocytes prior to ICSI.

During our studies there has been no registered complaints and no evidence that the product has been the cause of any serious adverse events in connection with its intended use.

Thus based on the clinical data presented and our experience with the SynVitro®Hyadase product we feel that the safety and effectiveness of the product for its intended use is shown in the present submission and the product is substantially equivalent to the predicated device Medi-Cult Hyaluronidase (K 991334).

Prepared and Submitted by:

April 17, 2003

Ronald G. Leonardi, Ph.D. Date
President
R & R REGISTRATIONS
P.O. Box 262069 San Diego, Ca 92131
619-586-0751

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 4 2003

Medi-Cult a/s
% Ronald G. Leonardi, Ph.D.
President
R & R Registrations
P.O. Box 262069
SAN DIEGO CA 92196-2069

Re: K031228
Trade/Device Name: SynVitro® Hyadase
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: 85 MQL
Dated: April 18, 2003
Received: April 24, 2003

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 (PMA), it may be subject to 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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

510(k) Number (if known) K031228

Device Name: SynVitro®Hyadase

INDICATIONS FOR USE:

For the removal of the cumulus complex and corona radiata surrounding the oocyte in preparation for ICSI.

(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)

Nancy C. Brogdan

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031228