K053646

5. 510(k) Summary

SAGE Assisted Reproduction Products™

SAGE In-Vitro Fertilization, Inc.
a CooperSurgical Company
[illegible]

JUL 14 2006

Submitter's name:	SAGE In-Vitro Fertilization
Address:	95 Corporate Drive Trumbull, CT 09911
Phone:	203-601-5200
Fax number:	203-601-4737
Name of contact person:	Grace Holland Regulatory Specialists, Inc 3722 Ave. Sausalito Irvine, CA 92606 Phone: 949-262-0411 Fax: 949-552-2821 Email: grace@regulatoryspecialists.com

Date the summary was prepared: December 26, 2005

Name of the device:	Oocyte Washing Medium
Trade or proprietary name:	Oocyte Washing Medium
Common or usual name:	Oocyte Washing Medium
Classification name:	Reproductive media

Name of the device:	Oocyte Maturation Medium
Trade or proprietary name:	Oocyte Maturation Medium
Common or usual name:	Oocyte Maturation Medium
Classification name:	Reproductive media

Name of the device:	Embryo Maintenance Medium
Trade or proprietary name:	Embryo Maintenance Medium
Common or usual name:	Embryo Maintenance Medium
Classification name:	Reproductive media

The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

Device	Ref#	Decided
MediCult IVM System	K041284	11/22/2004
Media For Gamete Preparation And Embryo Culture (Blastocyst Medium)	K002836	10/03/2000

Description of the devices:

Oocyte Washing Medium is a balanced salt solution containing nutrients, amino acids and vitamins to maintain immature oocytes during their collection and washing.

Oocyte Maturation Medium is a balanced salt solution containing nutrients, amino acids and vitamins for the in vitro culture of immature oocytes.

Embryo Maintenance Medium is a balanced salt solution containing nutrients and amino acids for maintaining embryos in culture.

Indications:

Oocyte Washing Medium: This medium is used for washing immature oocytes contained within cumulus-oocyte complexes (COCs), collected from the follicles before maturation in culture.

Oocyte Maturation Medium: This medium is used for maturation in culture of immature oocytes in an incubator.

Embryo Maintenance Medium: This medium is used for embryonic culture following insemination by intracytoplasmic sperm injection (ICSI).

Summary of the technological characteristics of our device compared to the predicate device:

The predicates and these devices were compared in the following areas and found to have equivalent technological characteristics and therefore are equivalent.

Formula
Indications for Use
Performance Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

JUL 14 2006

SAGE In-Vitro Fertilization, Inc.
% Ms. Grace Holland
Regulatory Specialist
Regulatory Specialists, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

Re: K053646
Trade/Device Name: IVM System
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: June 15, 2006
Received: June 20, 2006

Dear Ms. Holland:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 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

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): K053646

Device Name: IVM System

Indications for Use:

System for maturing immature oocytes of infertile women undergoing in vitro fertilization who for medical reasons cannot or choose not to undergo conventional ovarian stimulation using drugs.

Oocyte Washing Medium: This medium is used for washing immature oocytes contained within cumulus-oocyte complexes (COCs), collected from the follicles before maturation in culture.

Oocyte Maturation Medium: This medium is used for maturation in culture of immature oocytes in an incubator.

Embryo Maintenance: This medium is used for embryonic culture following insemination by intracytoplasmic sperm injection (ICSI).

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David G. Hoyman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053646

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