MAR 2 3 2006 K053494

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## 5. 510(k) Summary


Industriepark Noord 32 - 8730 Beernem - Belgium - Tel +32 50 79 18 05 - Fax +32 50 79 17 99

| | |
|---|---|
| Submitter's name: | FertiPro N.V. |
| Address: | Industriepark Noord 32<br>Beernem<br>West-Vlaanderen, Belgium 8730 |
| Phone: | +32 50 79 18 05 |
| Fax number: | +32 50 79 17 99 |
| Name of contact person: | Grace Holland<br>Regulatory Specialists, Inc<br>3722 Ave. Sausalito<br>Irvine, CA 92606<br>Phone: 949-262-0411<br>Fax: 949-552-2821<br>Email: grace@regulatoryspecialists.com |

Date the summary was prepared: December 13, 2005

| | |
|---|---|
| Name of the device: | Oil for Tissue Culture |
| Trade or proprietary name: | Oil for Tissue Culture |
| Common or usual name: | Mineral Oil |
| Classification name: | Reproductive media |

| | |
|---|---|
| Name of the device: | Gradient System |
| Trade or proprietary name: | Sil-Select Plus |
| Common or usual name: | Gradient System |
| Classification name: | Reproductive media |

| | |
|---|---|
| Name of the device: | SpermFreeze |
| Trade or proprietary name: | SpermFreeze |
| Common or usual name: | SpermFreeze |
| Classification name: | Reproductive media |

K055494
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The legally marketed devices to which we are claiming equivalence [807.92(a)(3)]:

| Device | Ref# | Decided |
|---|---|---|
| OIL FOR TISSUE CULTURE | K011462 | 06/13/2001 |
| ENHANCE-S PLUS H | K030116 | 02/12/2003 |
| ENHANCE SPERM FREEZE | K030117 | 03/20/2003 |

Description of the devices:

Oil For Tissue Culture is a colorless liquid paraffin.

Gradient System is a solution of silane-coated silica particles in Earle's Balanced Salts Solution (EBSS) with HEPES (pH buffer). Available in 45%, 90% and 100%.

SpermFreeze is a HEPES buffered freezing medium for use with human Sperm. It contains 0.4 % human serum albumin.

Indications:

Oil For Tissue Culture is used in covering tissue culture in in-vitro fertilization, embryo culture and micromanipulative procedures such as ICSI and assisted hatching.

Gradient System is used for separation and purification of human sperm for assisted reproduction procedures.

SpermFreeze is intended to be used as a cryopreservation medium for human sperm.

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 exact technological characteristics and to be equivalent.

Formula
Special controls
Packaging
Performance Testing

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

FertiPro N.V.
% Ms. Grace Holland
Regulatory Specialist
Regulatory Specialist, Inc.
3722 Ave. Sausalito
IRVINE CA 92606

Re: K053494
Trade/Device Name: Oil for Tissue Culture, Gradient System, and SpermFreeze
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: February 22, 2006
Received: February 24, 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.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

## 4. Indications for Use Statement

### Indications for Use

510(k) Number (if known): K053494

Device Name: Oil For Tissue Culture

Indications for Use:

Oil For Tissue Culture is used in covering tissue culture in in-vitro fertilization, embryo culture and micromanipulative procedures such as ICSI and assisted hatching.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053494

## Indications for Use

510(k) Number (if known): K053494

Device Name: Gradient System

Indications for Use:

Cell isolation media used for separation and purification of human sperm for assisted reproduction procedures.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053494

## Indications for Use

510(k) Number (if known): K053494

Device Name: SpermFreeze

Indications for Use:

SpermFreeze is intended to be used as a cryopreservation medium for human sperm.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053494