510k Summary

K113786
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OCT 26 2012

X. PREMARKET NOTIFICATION SUMMARY

Submitted by:

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Contact Person:

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Date Prepared:

October 19, 2012

Trade Name:

SpermFreeze Solution™

Common Name:

Media for cryopreservation of human sperm

Classification Name:

Reproductive Media and Supplements
(21 C.F.R. § 884.6180)

Predicate Device:

Sperm Freezing Medium (K070689)

Description of the Device:

SpermFreeze Solution™ is a device used for cryopreservation of human sperm. SpermFreeze Solution™ is developed to protect the spermatozoa during the freezing and thawing procedure. The solution contains glycerol as cryoprotectant and sucrose.

Indication for Use:

SpermFreeze Solution™ is indicated for cryopreservation of human sperm

Technological Characteristics:
SpermFreeze Solution™ is a device used for cryopreservation of human sperm. SpermFreeze Solution™ is developed to protect the spermatozoa during the freezing and thawing procedure. The solution contains glycerol as cryoprotectant and sucrose.

The SpermFreeze Solution™ device is a modification of the Sperm Freezing Medium (K070689). The technological characteristics of SpermFreeze Solution™ are similar to those of the predicate device. None of the differences between the predicate device and SpermFreeze Solution™ raise any new questions of safety or effectiveness.

Comparison of SpermFreeze Solution™ to the predicate device:
The SpermFreeze Solution™ device is a modification of the Sperm Freezing device (K070689) marketed by Life Global for the cryopreservation of human sperm. The SpermFreeze Solution™ device is similar to the predicate device in most aspects. Both devices have the same intended use and they contain essentially the same components. For example both devices use Human Serum Albumin supplementation and contain the cryopreservation ingredients Glycerol and Sucrose. Both devices have comparable performance test requirements. However the specification for the Human Sperm Survival Assay is ≥60% at 45 minutes exposure for SpermFreeze Solution™ while the specification for the predicate device is >80%. The lower HSSA specification does not raise any safety or effectiveness concerns since this assessment represents an indicator of appropriate device function and is within the range of HSSA specifications for other sperm contacting devices.

The main differences between the composition of SpermFreeze Solution™ and Sperm Freezing Medium are the following:

- SpermFreeze Solution™ contains CDLC (Chemically Defined Lipid Concentrate). CDCL contains cholesterol and fatty acids and is included to aid in maintenance of sperm cell membranes during the cryopreservation process. The addition of this material does not raise new types of questions as compared with other cleared sperm freezing medium containing lipids (e.g., from egg yolk).
- SpermFreeze Solution™ includes the broad-spectrum antibiotic Gentamicin to reduce the potential for culture contamination. Gentamicin is a common antibiotic used in assisted reproductive media and does not raise new types of safety or effectiveness questions.
- MOPS buffer is used instead of HEPES buffer. Both buffers are commonly used in IVF media and have a very similar function.

Successful cryopreservation of human spermatozoa has been demonstrated in clinical studies performed on SpermFreeze Solution™.

Non-clinical assessments:
Stability testing has been performed on SpermFreeze Solution™ to verify that the properties of the device are maintained during the entire shelf-life of 52 weeks.

Each manufacturing lot of SpermFreeze Solution™ is subject to the following tests:

Product property	Specification
pH at +20°C and ambient atmosphere	7.45 ± 0.2
Osmolality	2700 ± 300 mOsm/kg
Sterility Assurance Level (sterile filtration)	10^{-3}
Bacterial Endotoxins (LAL assay)	<0.5 EU/mL
Human Sperm Survival Assay	The acceptance criterion is ≥60% motility after 45 minutes exposure compared to the motility of the untreated sperm sample.

Pre –clinical data:
Preclinical studies on SpermFreeze Solution™ have been performed on human spermatozoa.

A human sperm survival cryopreservation assay was performed. The results were not significantly different between SpermFreeze Solution™ and the predicate device (SpermFreezing Medium).

A sperm chromatin structure assay was performed on donated semen. The test showed no statistically significant differences on DNA integrity between SpermFreeze Solution™ and the predicate device (SpermFreezing Medium).

Clinical data:
Clinical investigation was performed to investigate the spermatozoa's ability to fertilize the oocytes after being frozen with SpermFreeze Solution™.

In the study the fertilization rate and embryo development for oocytes which have been fertilized with frozen/thawed semen was compared with oocytes that have been fertilized with semen from fresh ejaculate.

Both the techniques of ICSI and standard IVF were included in the study. The fertilization rate was high for both ICSI and IVF, and with no statistical difference from the fresh group. The fertilization rate for ICSI was 64% in the SpermFreeze Solution™ group vs. 66% in the fresh group, and the fertilization rate for IVF was 83% in the SpermFreeze Solution™ group vs. 74% in the fresh group.

Pregnancy and delivery results were retrieved from patients with transfer of embryos in the ICSI group. The pregnancy rate of the SpermFreeze Solution™ group was not statistically different from the fresh group (50% in the SpermFreeze Solution™ group vs. 33% in the fresh group). All pregnancies resulted in delivery of healthy babies (delivery rate of 50% in the SpermFreeze Solution™ group vs. 33% in the fresh group).

In conclusion, results are of the same range in the SpermFreeze Solution™ group as that of fresh semen samples, and the study has confirmed that SpermFreeze Solution performs well in assisted reproductive technology treatment.

Conclusions from the pre-clinical and clinical testing:
No critical observations or deviations were found in the pre-clinical studies. The results from the survival and DNA integrity studies on human spermatozoa did not differ from results of the predicate device (SpermFreezing Medium).

From the clinical investigation it was concluded that SpermFreeze Solution™ can be used for cryopreservation of human spermatozoa. The device is considered to be safe and efficient to use for cryopreservation of semen.

Based on the findings during the pre-clinical and clinical studies SpermFreeze Solution™ has showed to be as safe, efficient and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

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% Ms. Nina Arvidsson
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Re: K113786
Trade/Device Name: SpermFreeze Solution™
Regulation Number: 21 CFR 884.6180
Regulation Name: Assisted reproductive media and supplements
Regulatory Class: Class II
Product Code: MQL
Dated: October 9, 2012
Received: October 11, 2012

Dear Ms. Arvidsson:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K113786

Device Name: SpermFreeze Solution™

Indications for Use: SpermFreeze Solution™ is indicated for cryopreservation of human sperm

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) *(Part 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, Gastro-Renal, and Urological Devices
510(k) Number K113786