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MAR - 3 2010

510(k) SUMMARY AS REQUIRED BY SECTION 807.92(c)

Submitted by:

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Date Prepared:

26 February 2010

Trade Name:

Vit Kit® - Freeze
Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage)

Vit Kit® - Thaw
Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage)

Common Name:

Embryo (PN zygotes to day 3 cleavage stage and blastocyst stage embryos) Vitrification cryopreservation media

Embryo (PN zygotes to day 3 cleavage stage and blastocyst stage embryos) Vitrification thawing and recovery media

Classification Name:

Reproductive Media (21 CFR § 884.6180)

Predicate Device:

RapidVit™ Cleave (K080446)

RapidWarm™ Warm (K080446)

Vit Kit® - Freeze (K060168)

Vit Kit® - Thaw (K060168)

Vitrification Kit (K073522)

Vitrification Warming Kit (K073522)

Cook IVF Freeze/Thaw Kit (K011157)

Description of the Device:

The five (5) media that comprise the two (2) kits, Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) and the Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage) are all based upon the modified formulation of Medium 199. The Medium 199 is HEPES buffered and contains 20% (v/v) DSS, 35µg/mL gentamicin and varying concentrations of DMSO, EG and sucrose. The two (2) freeze, ES and VS, media in the Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) are intended to be used sequentially, for the preparation for, and cryopreservation of, PN, day 3 cleavage stage embryos and blastocyst stage embryos. ES is used in preparation for freezing and contains 7.5 % (v/v) DMSO and EG. VS is to be used during cryostorage and contains 15% (v/v) DMSO and EG and 0.5M sucrose.

The three (3) thaw, TS, DS and WS, media in the Vit Kit®- Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage) are also intended for sequential use in the thawing and recovery of cryopreserved human embryo. The first medium used in the thawing process, TS, contains 1.0M sucrose. The second medium, DS, contains 0.5M sucrose. The third medium, WS, contains no sucrose.

Intended Use:

Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) is intended for use in the vitrification of pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage) is intended for use in the thawing and recovery of vitrified pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Technological Characteristics:

Embryos are routinely stored for use in future assisted reproductive procedures. In some instances, excess eggs will be retrieved from the patient, and fertilized. If development of these fertilized eggs indicates a potential for viability during implantation, they may be frozen for future use. In the event that the current transfer is unsuccessful, and does not result in a clinical pregnancy, the patient has embryos in reserve that may be used for implantation in future procedures. Embryos are also routinely frozen when patients have a history of unsuccessful implantation procedures, and also for those patients who desire multiple children. Media to protect the embryos during the preparation for cryopreservation, during storage, and ultimate thawing and recovery are, therefore, different in composition from media used for gamete retrieval, during fertilization and implantation.

The media in the Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) ES and VS, are designed to be used sequentially for the preparation of vitrified PN zygotes, day 3 cleavage stage embryos and blastocyst stage embryos for cryopreservation, as the protective media during cryostorage.

The media in the Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage) TS, DS and WS, are also designed for sequential use, in the thawing and recovery of cryopreserved vitrified PN zygotes, day 3 cleavage stage embryos and blastocyst stage embryos. None of the media are intended to contact the patient.

The predicate devices, RapidVit™ Cleave and RapidWarm™ Cleave (K080446), RapidVit™ Cleave and RapidWarm™ Cleave (K080446), and the Irvine Scientific Vit™ - Freeze and Vit™ - Thaw (K060168) are all designed for vitrification. The Cook IVF Freeze/Thaw Kits (K011157) was designed as a slow freeze kit.

The predicate devices referenced above are all similar in that they incorporate a basal media (Modified HTF, Medium 199) that contain amino acids, non-essential amino acids that is buffered (HEPES, MOPs), permeating (1.5 M Propainediol, Ethylene Glycol (EG), DMSO), a non-permeating cryoprotectant (Sucrose), protein (human serum albumin), and antibiotic (Gentamicin). The basal media that comprise the predicate devices are not intended for the culture of the specimens that are vitrified or cryopreserved by slow freezing. However, the basal media are all similar in that they contain energy substrates such as lactate, pyruvate and glucose.

The predicate devices each incorporate a stepwise method for exposing specimen(s) to the media to prepare them for slow-freezing or vitrification. Likewise, each of the predicate devices are comprised of a stepwise method for thawing the slow-frozen or vitrified specimen(s).

The type of permeating cryoprotectants that encompass each of the predicate devices have been used for many years for varying types of cryopreservation. The cryoprotectant used is dependent on the method of cryopreservation. Vitrification media are comprised of a combination of permeating cryoprotectants such as ethylene glycol, propanediol and DMSO. Slow freezing media are typically comprised of one cryoprotectant. It has been published in an article by

Al-Hasani, et. al.[1] that cryoprotectant mixtures might have better results than solutions containing one permeable cyroprotectant, Vajta, et. al.[2]

The predicate devices, RapidVit™ Cleave and RapidWarm™ Cleave (K080446), were cleared in November 2008 with the intended use for vitrification of day 3 cleavage stage embryos and warming of vitrified day 3 cleavage stage embryos respectively. The predicate device for the RapidVit™ Cleave and RapidWarm™ Cleave (K080446) was the Irvine Scientific Vit™ - Freeze and Vit™ - Thaw (K060168) cleared in April 2006 with the intended use in the assisted reproductive procedure of vitrification and thawing blastocysts.

The predicate device, Cook IVF Freeze/Thaw Kits (K011157) were cleared in May 2001 with the intended for use in the cryopreservation, slow freezing, of zygotes or embryos and thawing of cryopreserved zygotes or embryos, respectively, that are intended for use during in vitro fertilization procedures.

The predicate devices, RapidVit™ Cleave and RapidWarm™ Cleave (K080446) and Vit Kit® - Freeze and Vit Kit® - Thaw (K060168), like the Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) and Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage) are comprised of embryo-physiological solutions that are supplemented with permeable and non-permeable cryoprotectants. Both the predicate devices and the Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) and Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage) are subjected to the same methods of control and to a significant degree are comprised of the same components. The storage conditions and manner in which the products are used are similar. All the devices have a sterility assurance level of 10^{-3}.

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[1] Al-Hasani, Safaa, et. al., Three years of routine vitrification of human zygotes: is it still fair to advocate slow-rate freezing?, Reproductive BioMedicine Online, Vol. 14, No. 3, 2007, p. 288-293.
[2] Vajta G., Nagy, ZP, Are programmable freezers still needed in the embryo laboratory? Review on vitrification, Reproductive BioMedicine Online, Vol. 12, 2006, 779 – 796.

The composition of the media and their concentrations, where available, that comprise each of the predicate devices, RapidVit™ Cleave (K080446), Vit Kit® - Freeze (K060168), Vitrification Kit (K073522), the Cook IVF Freeze/Thaw Kit (K011157) and the proposed device, Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) are presented in **Table 1** below:

Table 1: Vitrification Kits Predicate Device Component Comparison

Vitrification Kits									
Device	**Freezing Method**	**Cryoprotectant**				**Media Components**			
		Ethylene Glycol	**DMSO**	**Sucrose**	**Other**	**Amino Acids**	**NEAA[3]**	**Gentamicin**	**Protein HSA[4]**
RapidVit™ Cleave (K080446)	Vitrification	+	-	+	1, 2 – propanediol	+	+	+	+
Vit Kit® - Freeze (K060168)	Vitrification	+[5]	+[5]	+[6]	-	+	+	+	+
Vitrification Kit (K073522)	Vitrification	+[5]	+[5]	+[7]	-	+	+	+	+
Cook IVF Freeze/Thaw Kit (K011157)	Slow Freeze	-	-	+	1,2 propanediol	+	+	+	+
Vit Kit®- Freeze (K073522)	Vitrification	+[5]	+[5]	+[6]	-	+	+	+	+

[3] NEAA – non-essential amino acids
[4] HSA – human serum albumin
[5] Used at two (2) concentrations, 7.5% (v/v) in the Equilibration Solution and 15% (v/v) in the Vitrification Solution
[6] 0.5M sucrose in the Vitrification Solution
[7] 0.6M sucrose in the Vitrification Solution

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The composition of the media and their concentrations, where available, that comprise each of the predicate devices, RapidVit™ Warm (K080446), Vit Kit® - Thaw (K060168), Vitrification Warming Kit (K073522), the Cook IVF Freeze/Thaw Kit (K011157), and the proposed device, Vit Kit® - Thaw, Vitrification Thaw Kit for Embyros (PN through Blastocyst Stage) are presented in **Table 2** below:

Table 2: Vitrification Warm/Thaw/Warming Kits Predicate Device Component Comparison

Vitrification Warm/Thaw/Warming Kits								
Device	**Media Components**							
	Sucrose	**Amino Acids**	**NEAA[3]**	**Lactate**	**Pyruvate**	**Glucose**	**Gentamicin**	**Protein HSA[4]**
RapidVit™ Warm (K080446)	+	+	+	+	+	+	+	+
Vit Kit® - Thaw (K060168)	+[8]	+	+	+	+	+	+	+
Vitrification Warming Kit (K073522)	+[9]	+	+	+	+	+	+	+
Cook IVF Freeze/Thaw Kit (K011157)	+	+	+	+	+	+	+	+
Vit Kit® - Thaw (K073522)	+[8]	+	+	+	+	+	+	+

[8] 1.0M Sucrose in the Thawing Solution and 0.5M Sucrose in the Dilution Solution,
[9] 1.0M Sucrose Warming Solution and 0.5M Sucrose Warming Solution

Additional Information:

Endotoxin, mouse embryo freezing and recovery assay performance and sterility tests will be performed as a condition of release for these products. Results of all release assays performed will be reported on a lot-specific certificate of analysis, and will be indicated on the labeling.

Conclusion:

In the clinical data that was presented in the Comparison to Predicate Device summary presented on page 68 there have been a total of thirty (30) births (10 singletons; 9 deliveries = 2 singletons, 7 twins, 2 triplets; 11 deliveries = number of children from the deliveries not known) for vitrified pronuclear stage zygotes and day 3 embryos. In addition, at the time of publication of the articles there are fifty-two (52) ongoing pregnancies (37 pregnancies for Kumasako, et. al.[12]; 15 pregnancies for Al-Hasani, et. al[1]) reported following use of 2PN embryos and one hundred-thirty seven (137) ongoing pregnancies (136 pregnancies for Kuwayama, et. al[8]; 1 pregnancy for Oakes, et. al.[11]).

With regards to the intended use of the Irvine Scientific the Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) and Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage) for pronuclear zygotes (PN) also presented in the Comparison to Predicate Device Summary presented on page 68 there specifically have been ten (10) healthy births (19 babies = 1 singleton and 9 deliveries = 18 babies) and fifty-two (52) ongoing pregnancies (37 pregnancies for Kumasako, et. al.[12]; 15 pregnancies for Al-Hasani, et. al[1]).

Based upon the clinical data that was summarized it has been demonstrated that the Irvine Scientific the Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) and Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage) device are substantially equivalent to the

predicate device, RapidVit™ Cleave and RapidWarm™ Cleave (K080446) in which the study resulted in the births of two (2) sets of twins and six (6) singletons, a total of eight (8) births and are suitable for their intended use, and meet the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket number 97N-0335.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

MAR - 3 2010

Ms. Jayme Yamaguchi-Owens
Regulatory Affairs Manager
Irvine Scientific Sales Co., Inc.
2511 Daimler Street
SANTA ANA CA 92705-5588

Re: K093273
Trade/Device Name: VitKit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage), VitKit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage)
Regulation Number: 21 CFR §884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: February 3, 2010
Received: February 12, 2010

Dear Ms. Yamaguchi-Owens:

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,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Irvine Scientific February 24, 2010

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K093273

Device Name: Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage)

Indications for Use:

Vit Kit® - Freeze, Vitrification Freeze Kit for Embryos (PN through Blastocyst Stage) is intended for use in the vitrification of pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Prescription Use ___X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR § 801 Subpart D) (21 CFR § 807 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 K093273

Irvine Scientific March 1, 2010

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K093273

Device Name: Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage)

Indications for Use:

Vit Kit® - Thaw, Vitrification Thaw Kit for Embryos (PN through Blastocyst Stage Embryos) is intended for use in the thawing of vitrified pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR § 801 Subpart D) (21 CFR § 807 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 K093273