DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 4, 2016

Irvine Scientific
Jayme Yamaguchi-Owens
Regulatory Affairs Manager
2511 Daimler St
Santa Ana, CA 92705

Re: K160006
Trade/Device Name: Vit Kit-freeze Oocytes, Embryos and PN Zygotes Vitrification Freeze Kit,
Vit Kit-thaw Oocytes, Embryos and PN Zygotes Vitrification Thaw Kit
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: Class II
Product Code: MQL
Dated: April 1, 2016
Received: April 5, 2016

Dear Jayme 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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Herbert P. Lerner -S

for 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160006

Device Name
Vit Kit® - Freeze (Vitrification Freeze Kit)

Indications for Use *(Describe)*
Vit Kit® - Freeze (Vitrification Freeze Kit) is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160006

Device Name
Vit Kit® - Thaw (Vitrification Thaw Kit)

Indications for Use *(Describe)*
Vit Kit® - Thaw (Vitrification Thaw Kit) is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Submitters Name and Address:	Irvine Scientific Sales Co., Inc. 2511 Daimler Street Santa Ana, CA 92705 Telephone: 800-437-5706 Facsimile: 949-261-6522
Manufacturing Site:	2511 Daimler Street Santa Ana, CA 92705
Contact Person:	Jayme Yamaguchi-Owens Irvine Scientific Sales Co., Inc. 2511 Daimler Street Santa Ana, CA 92705 Telephone: 800-437-5706 Facsimile: 949-261-6522 Email: jfy@irvinesci.com
Date Prepared:	May 4, 2016
Establishment Registration Number:	2022379
510(k):	K160006
Trade or Proprietary Name:	Vit Kit® - Freeze Oocytes, Embryos and PN zygotes Vitrification Freeze Kit Vit Kit® - Thaw Oocytes, Embryos and PN zygotes Vitrification Thaw Kit
Common Name:	Vitrification Freezing and Thawing Kits
Device Regulation:	21 CFR § 884.6180
Device Classification:	Class II
Product Code:	MQL
Predicate Device:	Vit Kit® - Freeze, Irvine Scientific (K093273) Vit Kit® - Thaw, Irvine Scientific (K093273)

Device Description:

The five media that comprise the two kits, Vit Kit® - Freeze and the Vit Kit® - Thaw are all based upon a modified formulation of Medium 199. Medium 199 is HEPES buffered and contains 20% (v/v) dextran substitute supplement (DSS), 35μg/mL gentamicin and varying concentrations of dimethyl sulfoxide (DMSO), ethylene glycol (EG), and sucrose. The two freeze media in the Vit Kit® - Freeze are intended to be used sequentially, for the preparation and cryopreservation of PN, day 3 cleavage stage, and blastocyst stage embryos and oocytes.

The three thaw media in the Vit Kit®- Thaw are intended for sequential use in the thawing and recovery of cryopreserved human PN, cleavage stage, and blastocyst embryos and oocytes.

Indications for Use:

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

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

Vit Kit® - Freeze and Vit Kit® - Thaw was previously cleared under K093273 with the intended use for vitrification of pronuclear (PN) through day 3 cleavage stage embryos and blastocyst stage embryos and thawing/warming of vitrified PN through day 3 cleavage stage embryos and blastocyst stage embryos respectively.

The purpose of this submission is to expand the indication for use of the cleared Vit Kit® - Freeze and Vit Kit® - Thaw (K093273) to include oocytes (MII).

The expansion of the indication for use statement to include oocytes in the current submission does not alter the intended use and therapeutic effect of the device (cryopreservation of extra embryos/gametes for use at a later time).

Comparison of Technological Characteristics with the Predicate Device:

The media in the Vit Kit® - Freeze and Vit Kit® - Thaw are designed to be used sequentially for the vitrification and thawing of MII oocytes, PN zygotes, day 3 cleavage stage and blastocyst stage embryos for cryopreservation during assisted reproduction procedures. None of the media are intended to contact the patient.

The composition of the media that comprise the predicate device Vit Kit® - Freeze and Vit Kit® - Thaw (K093273) and the proposed device, Vit Kit® - Freeze and Vit Kit® - Thaw (K160006) are identical as presented in the tables below:

Table 1: Vitrification Freeze Kit Component Comparison

Vitrification Kits							
Device	**Cryoprotectant**			**Media Components**			
	Ethylene Glycol[1]	**DMSO**[7]	**Sucrose**[2]	**M199**		**Gentamicin**	**Protein**
				Amino Acids	**NEAA**[3]		
Vit Kit® - Freeze (K093273)	+	+	+	+	+	+	+
Vit Kit® - Freeze (K160006)	+	+	+	+	+	+	+

[1] Used at two (2) concentrations, 7.5% (v/v) in the Equilibration Solution and 15% (v/v) in the Vitrification Solution
[2] Used at one (1) concentrations, 0.5M in the Vitrification Solution
[3] NEAA – non-essential amino acids

Table 2: Vitrification Thaw Kit Component Comparison

Vitrification Warm/Thaw/Warming Kits					
Device	**Media Components**				
	Sucrose[4]	**M199**		**Gentamicin**	**Protein**
		Amino Acids	**NEAA**		
Vit Kit® - Thaw (K093273)	+	+	+	+	+
Vit Kit® - Thaw (K160006)	+	+	+	+	+

The product specifications for the Vit Kit® - Freeze and Vit Kit® - Thaw are identical to the predicate device, as described in the table below:

Table 1: Vit Kit® - Freeze Kit and Vit Kit® - Thaw Product Specifications

Final Product Test Specification	**Vit Kit® - Freeze K093273 K160006**		**Vit Kit® - Thaw K093273 K160006**		
	ES Freeze 90131	**VS Freeze 90132**	**TS Thaw 90134**	**DS Thaw 90135**	**WS Thaw 90136**
Appearance	Pass	Pass	Pass	Pass	Pass
pH	7.05 – 7.54	7.05 – 7.54	7.05 – 7.44	7.05 – 7.44	7.05 – 7.44
Osmolality ($mOsm/KgH_2O$)	1,055 – 1,445	1,100 – 1,588	1,732 - 1,912	857 – 910	268 – 292
Endotoxin (EU/mL)	0.03 – 0.60	0.03 – 0.60	0.03 -0.60	0.03 -0.60	0.03 -0.60
Sterility	Pass	Pass	Pass	Pass	Pass
Modified Mouse Embryo Assay (% of Control)	80 – 100	80 – 100	80 – 100	80 – 100	80 – 100

[4] Sucrose = a non-permeating cryoprotectant used at two (2) concentrations, 1.0M in the Thawing Solution, 0.5M in the Dilution Solution.

Final Product Test Specification	Vit Kit® - Freeze K093273 K160006		Vit Kit® - Thaw K093273 K160006		
	ES Freeze 90131	VS Freeze 90132	TS Thaw 90134	DS Thaw 90135	WS Thaw 90136
Albumin Recovery (%)	85 - 200	85 - 200	85 - 200	85 - 200	85 - 200

The technological characteristics of the Vit Kit® - Freeze and Vit Kit® - Thaw Kit are comparable to the predicate device, do not impact substantial equivalence, and do not raise new issues regarding safety or effectiveness.

Non-clinical Performance Data:

Vit Kit® - Freeze and Vit Kit® - Thaw media are tested using the one cell mouse embryo assay prior to their release for sale. This assay assures that the product is both functional for its intended use, the support of embryonic growth, and that no toxic components are present in the formulation.

Endotoxin, albumin recovery assay, pH, osmolality, appearance and sterility testing are also performed as a condition of release for Vit Kit® - Freeze and Vit Kit® - Thaw media. Results of all release assays performed are reported on a lot-specific certificate of analysis, and are indicated on the labeling.

In addition, shelf-life testing has been performed to ensure no loss of functionality or sterility at the end of the proposed shelf-life.

Clinical Performance Data:

To support substantial equivalence, a clinical study was performed to assess the clinical efficacy of oocyte cryopreservation using the Vit Kit® - Freeze and Vit Kit® - Thaw as compared to non-cryopreserved (fresh) oocytes.

The study was a prospective, multicenter study comprised of up to 400 patients. Inclusion criteria encompassed some of the following: Infertile women < 37 years of age in good general physical and mental health and a normal BMI (≤ 27); Voluntarily wishing to conceive or preserve fertility potential with excess MII oocytes remaining

after a fresh IVF treatment cycle with a minimum of six (6) freezable MII oocytes required with fertilization of oocytes by ICSI only. Exclusion criteria included some of the following: Couples for whom the male partner requires testicular or epididymal sperm retrieval; Uncorrected hydrosalpinx or abnormal uterine cavity; History of hypo-responsiveness or ovarian stimulation or complications related to tolerance to OCP's, Gonadotropins, Progesterone or estrogen or a medical condition that is contraindicated to pregnancy or gonadotropin therapy (examples: allergies, immune deficiency, etc.).

The clinical data demonstrated the comparability between the frozen oocyte and fresh oocyte transfers with regards to the following criteria:

- % Implantation Rate/Transfer
- % Pregnancy Rate/Transfer

The % fertilized was observed to be 15% lower for frozen oocytes when compared to fresh oocytes; however, it did not impact the % Implantation Rate/Transfer and % Pregnancy Rate/Transfer, which were comparable to fresh oocytes. The % Live Births/Transfer and % Live Births/Pregnancy were higher for the frozen oocytes when compared to fresh oocytes. Based upon the clinical date, the safety and the effectiveness of the Vit Kit® - Freeze and Vit Kit® - Thaw were demonstrated.

In addition, the clinical data was compared to the current National Assisted Reproductive Technology (ART) Success Rates published in the Centers for Disease Control and Prevention Report of 2013 National Summary in August 2015. This comparison revealed that for the fresh oocytes, the % Live Births/Transfer rates from the clinical study were lower, and the % Live Births/Pregnancy rates were comparable to the CDC data. For frozen oocytes, the % Live Births/Transfer rates were similar and the % Live Births/Pregnancy rates were significantly higher in the clinical study when compared to the CDC data.

Finally, peer-reviewed published literature was provided to support the expansion of the Indications for Use to include oocyte vitrification. Several of these publications provided

clinical data of oocyte vitrification using the subject device. The other published literature included studies that were performed using identical cryoprotectants (ethylene glycol, DMSO, and sucrose) at the same or similar concentrations to those used in the subject device. The clinical study data was compared to the published literature with regards to the number of patients participating, oocyte survival rates, fertilization rates, pregnancy rates, livebirth/transfers, and the number of live births reports for frozen and fresh oocytes.

Based upon the information provided in the published literature, the success rates reported in regards to fertilization rates, pregnancy rates, live birth/transfers and live birth rates were equivalent to or comparable to the Vit Kit® - Freeze and Vit Kit® - Thaw. Therefore, the published clinical data provided supports the substantial equivalence of the Vit Kit® - Freeze and Vit Kit® - Thaw.

Conclusion:

The results of the testing described above provide a reasonable assurance that Vit Kit® - Freeze and Vit Kit® - Thaw is as safe and effective as the predicate device and supports and determination of substantial equivalence