JUL 19 2012

510(k) SUMMARY AS REQUIRED BY 21 CR § 807.87(h)

Submitter's Name and Address:	Irvine Scientific Sales Co., Inc. 2511 Daimler Street Santa Ana, CA 92705-5588
Manufacturing Site:	2511 Daimler Street Santa Ana, CA 92705-5588
Contact Person:	Jayme Yamaguchi-Owens Regulatory Affairs Manager Irvine Scientific 2511 Daimler Street Santa Ana, CA 92705-5588 Tel: 949-261-7800 ext 254 Fax: 949-261-6522 Email: jfy@irvinesci.com
Date of Application:	May 24, 2012
Establishment Registration Number:	2022379
510(k):	K121572
Trade or Proprietary Name:	Continuous Single Culture™ Complete
Device Name:	In Vitro embryo culture medium
Device Classification:	Reproductive Media and Supplements
Device Regulation:	21 CFR § 884.6180
Device Classification:	Class II (Special Controls)
Product Code:	MQL
Predicate Device:	Single Step Medium™, K072609
Performance Standards:	None established

Purpose:

Purpose of this application is to obtain 510(k) marketing clearance for the Continuous Single Culture™ Complete.

Indication for Use:

Continuous Single Culture™ Complete is intended for use as a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro.

Description of the Device:

The Continuous Single Culture™ Complete is based upon the Single Step Medium™ (K072609) formulation that is supplemented with Human Serum Albumin, H.S.A. The Continuous Single Culture™ Complete is composed of a balanced mixture of salts, amino acids and other nutrients that have been shown to support embryo development. The Continuous Single Culture™ Complete is designed to be used as a culture media for fertilization and for development of embryos until the desired developmental stage (up to 5/6 days). Selected embryos are then moved to an embryo transfer media prior to transfer to the uterus.

The Continuous Single Culture™ Complete is supplied in liquid form, and contains gentamicin sulfate as a preservative and a therapeutic grade of Human Serum Albumin (K983584). Liquid Continuous Single Culture™ Complete is supplied in a fill volume of 20 mL.

Continuous Single Culture™ Complete has utility as a culture medium from fertilization through day 5/6 of development. The fertilized oocyte (zygote) is allowed to grow in the culture dish, supported by a culture medium and an appropriate protein supplement, in a carbon dioxide incubator at 37°C until the desired stage of development is achieved. Selected embryos are then moved to an embryo transfer media prior to transfer to the uterus.

Continuous Single Culture™ Complete is supplied as a ready to use liquid in 20 mL bottles.

Technological Characteristics:

After allowing the fertilized zygote to develop in vitro in Continuous Single Culture™ Complete, the embryo is removed from the culture dish. It is placed into a fresh dish containing Continuous Single Culture™ Complete. The dish is then returned to the incubator, and the embryo is allowed to continue develop in vitro. If a medium change is desired for embryo culture beyond day 3, after 48 hours of embryo culture (of the fertilized embryos), the embryos should be transferred into a new dish of fresh pre-equilibrated Continuous Single Culture™ Complete. After the desired stage of development is obtained selected embryos are then moved to an embryo transfer media prior to transfer to the uterus

Continuous Single Culture™ Complete is similar to Single Step Medium™ (K072609) it is intended for use in assisted reproductive technology procedures that involve the manipulation of gametes or embryos that is supplemented with a protein such as H.S.A. (K983584).

Performance Data:

Continuous Single Culture™ Complete is assayed by one (1) -cell mouse embryo assay (MEA) prior to release to the market. This assay assures that the product is functional for its intended use, the support of embryonic growth, and that embryotoxic components are not present in the formulation..

Continuous Single Culture™ Complete is also assayed by human sperm survival assay (HSSA) was also performed prior to release to the market. This assay also assures that the product is both functional for its intended use with regards to sperm wash procedure and that no sperm-toxic components are present in the formulation.

In addition, performance testing of the product includes pH, osmolality, sterility, and endotoxin testing. These tests demonstrate quality and the consistency in

each lot of Continuous Single Culture™ Complete that is manufactured. These tests also support the equivalence of the proposed device to the predicate device.

Nonclinical Tests:

One (1) -cell MEA was performed on the Continuous Single Culture™ Complete as part of the design validation. Testing was performed at three (3) different test facilities after continuous culture in Continuous Single Culture™ Complete up to 96 hours.

In addition, HSSA was also performed on donor specimens at three (3) different test facilities. The donor specimens were initially processed by gradient separation and resulting motile specimens were equally divided and the average % motility after 24 hours at 37°C in ambient air was determined as compared to the control.

The field evaluations demonstrate that the Continuous Single Culture™ Complete was "equal" to the proven control medium (predicate device) of Single Step Medium™ (K072609).

Additional Information:

Endotoxin, mouse embryo assay, human sperm survival assay, albumin recovery assay, pH, osmolality, appearance and sterility testing will be performed as a condition of release for Continuous Single Culture™ Complete. Results of all release assays performed will be reported on a lot-specific certificate of analysis, and will be indicated on the labeling.

Conclusion:

The predicate device, Single Step Medium™ (K072609) needs to be supplemented with a protein prior to use and it is a common practice for media to be formulated with a protein for use in ART procedures. Therefore, the addition of HSA to the device would not raise new types of safety of effectiveness questions.

A comparison of the Predicate Device Intended Use, Product Formula and Product Specifications are summarized below that demonstrate substantial equivalence.

Table 1: Predicate Device Intended Use Comparison

Product Name	K#	Fertilization Medium	Culture of Embryos to Day 5/6	Protein Supplement
Single Step Medium™	K072609	+	+	–

The intended use between the predicate device and the proposed device are the same in that the medium can be used from fertilization and culture of embryos to day 5/6.

Table 2: Predicate Device Product Formula Comparison

Item #	Raw Material and CAS No.	Single Step Medium™ (K072609)	CSC™ Complete
		UOM/L	
1	WFI Water, produced in house	+	+
2	Phenol red, sodium salt [34487-61-1]	+	+
3	Sodium bicarbonate [144-55-8]	+	+
4	EDTA, disodium salt [6381-92-6]	+	+
5	Sodium Citrate, dehydrate [6132-04-3]	+	+
6	5N Hydrochloric acid [7647-01-0] (for pH adjustment only)	–	+
7	20% Human Serum Albumin	–	+
8	L- Lactic Acid Sodium, Salt [867-56-1]	–	+
9	DL-Lactic Acid Sodium, Salt [72-17-3]	+	-
10	Sodium Chloride [7647-14-5]	+	+
11	Potassium Chloride [7447-40-7]	+	+
12	Dextrose, anhydrous	+	+

Item #	Raw Material and CAS No.	Single Step Medium™ (K072609)	CSC™ Complete
		UOM/L	
	[50-99-7]		
13	Magnesium sulfate, anhydrous [7487-88-9]	+	+
14	Potassium Phosphate, monobasic [7778-77-0]	+	+
15	Pyruvic Acid, Na Salt [113-24-6]	+	+
16	L-Alanine [56-41-7]	+	+
17	L-Arginine HCl [1119-34-2]	+	+
18	L-Asparagine monohydrate [5794-13-8]	+	+
19	L-Aspartic acid [56-84-8]	+	+
20	L-Glutamic acid [56-86-0]	+	+
21	Glycine [56-40-6]	+	+
22	L-Histidine HCl monohydrate [5934-29-2]	+	+
23	L-Isoleucine [73-32-5]	+	+
24	L-Leucine [61-90-5]	+	+
25	L-Lysine HCl [657-27-2]	+	+
26	L-Methionine [63-68-3]	+	+
27	L-Phenylalanine [63-91-2]	+	+
28	L-Proline [147-85-3]	+	+
29	L-Serine [56-45-1]	+	+
30	L-Taurine [107-35-7]	+	–
31	L-Threonine [72-19-5]	+	+
32	L-Tryptophan [73-22-3]	+	+
33	L-Tyrosine disodium, dihydrate [69847-45-6]	+	+

Item #	Raw Material and CAS No.	Single Step Medium™ (K072609)	CSC™ Complete
		UOM/L	
34	L-Valine [72-18-4]	+	+
35	Calcium chloride, anhydrous [10043-52-4]	+	+
36	L_Cystine 2HCl [30925-07-6]	–	+
37	L-Cysteine HCl.H_2O [7048-04-6]	+	–
38	Alanyl-Glutamine [39537-023-0]	+	+
39	Gentamicin sulfate [1405-41-0]	+	+

The formulation comparison between the predicate device and the proposed device are equivalent with the exception of three (3) components (raw materials). The predicate device contains taurine and the proposed device does not. It was identified that in the presence of other amino acids taurine provided no specific benefit.

The predicate device contains L-Cysteine and the proposed device contains L-Cystine. It was identified that the L-Cystine is a more stable amino acid than the L-Cysteine during the development of the proposed device.

The predicate device contains DL-Lactic Acid and the proposed device contains L-Lactic acid. IT was identified that the L-Lactic acid is the active form of DL-Lactic acid.

The component differences between the predicate and the proposed devices have been addressed as the performance of the Continuous Single Culture™ Complete was verified for performance during product development.

Table 3: Predicate Device Product Specification Comparison

Specification	Single Step Medium™ (K072609)	Continuous Single Culture™ Complete
pH	7.25 – 7.54	7.25 – 7.54
Osmolality	260 – 270 mOsm/KgH_2O	260 – 270 mOsm/KgH_2O

Specification	Single Step Medium™ (K072609)	Continuous Single Culture™ Complete
Sterility	Pass	Pass
Endotoxin	≤ 0.25 EU/mL	≤ 0.25 EU/mL
MEA	≥ 80%	≥ 80% expanded blastocyst at 96 hours
HSSA	NT[1]	≥ 70% of original motility at 24 hours

The product specifications for the predicate and the proposed device are identical with the exception of the HSSA which was added to the product specification for the proposed device as it is within the intended use of the product.

The conclusion from the performance testing, intended use comparison, product formulation comparison and test specification comparison as well as the nonclinical and clinical data demonstrates that the Continuous Single Culture™ Complete is suitable for its intended use, and meets the criteria in the comparison to predicate device in which substantial equivalence has been demonstrated, and meets the criteria outlined in the Notice of Final Rule, 63 FR 48428, Docket Number 97N-0335.

[1] NT – Not Tested

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

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

JUL 19 2012

Re: K121572
Trade/Device Name: Continuous Single Culture™ Complete
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: May 24, 2012
Received: May 29, 2012

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,

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

Irvine Scientific May 24, 2012

INDICATIONS FOR USE STATEMENT (page 1 of 1)

510(K) Number: K121572

Device Name: Continuous Single Culture™ Complete

Indications for Use:

Continuous Single Culture™ Complete is intended for use as a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro.

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

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Benjamin R. Fisher 19 July 2012
(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K121572