January 13, 2022

Irvine Scientific Sales Co., Inc.
Jayme Yamaguchi-Owens
Regulatory Affairs Manager
2511 Daimler Street
Santa Ana, CA 92705

Re: K170602
Trade/Device Name: Continuous Single Culture®-NX Complete (CSCM-NXC)
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL

Dear Jayme Yamaguchi-Owens:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 7, 2017. Specifically, FDA is updating this SE Letter to include the correct version of the 510(k) Summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Monica Garcia, Ph.D., OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology Devices, (240) 402-2791, monica.garcia@fda.hhs.gov.

Sincerely,

Monica D. Garcia -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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

June 7, 2017

Irvine Scientific Sales Co., Inc.
Jayme Yamaguchi-Owens
Regulatory Affairs Manager
2511 Daimler Street
Santa Ana, CA 92705

Re: K170602
Trade/Device Name: Continuous Single Culture®-NX Complete (CSCM-NXC)
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: May 18, 2017
Received: May 19, 2017

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,

Benjamin R. Fisher -S

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)*
K170602

Device Name
Continuous Single Culture®-NX Complete (CSCM-NXC)

Indications for Use *(Describe)*
The Continuous Single Culture®-NX Complete (CSCM-NXC) is intended for use as a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro. This device can be used for transfer of embryos to the uterus.

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

I. General Information on Submitter

Submitter/Address: Irvine Scientific Sales Co., Inc.
2511 Daimler Street
Santa Ana, CA 92705
Telephone: 800-437-5706
Facsimile: 949-261-6522

Contact Person: Jayme Yamaguchi-Owens
Regulatory Affairs Manager
Irvine Scientific
2511 Daimler Street
Santa Ana, CA 92705
Tel: 949-261-7800 ext 254
Fax: 949-261-6522
Email: jfy@irvinesci.com

II. Date Prepared: June 6, 2017

III. General Information on Device

Device Name: Continuous Single Culture®-NX Complete (CSCM-NXC)

Common Name: Embryo Culture Media

Classification Name: Reproductive Media and Supplements (21 CFR 884.6180)

Product code: MQL (Media, Reproductive)

Regulatory Class: II

IV. Predicate Device:

Continuous Single Culture Complete (K121572), manufactured by Irvine Scientific Sales Co., Inc. This predicate device has not been subject to any design related recalls.

V. Description of the Device:

The Continuous Single Culture®-NX Complete (CSCM-NXC) is a culture medium using a formulation modified from the predicate device. It is intended for culture of embryos from fertilization to balstulation and transfer of embryos to the uterus. This medium consists of salts, energy substrates, amino acids, buffering agents, nutrients supplements, antibiotics, and human serum albumin.

This product is a single-use device supplied in a fill volume of 20 mL. It is aseptically filled into the sterilized bottle and has a sterility assurance level (SAL) of 10^{-3}. The product is tested for pH, osmolality, embryotoxicity, spermtoxicity, endotoxin, and sterility before lot release. The product has a four-month shelf-life and remains stable for four weeks after open/close of bottle, when it is stored at 2-8°C.

VI. Indication for Use:

The Continuous Single Culture®-NX Complete (CSCM-NXC) is intended for use as a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro. This device can be used for transfer of embryos to the uterus.

VII. Comparison of Intended Use and Technological Characteristics of Subject and Predicate Devices

Device & Predicate Device(s):	K170602 (subject device)	K121572 (predicate device)
Indications for Use	The Continuous Single Culture®-NX Complete (CSCM-NXC) is intended for use as a culture medium for human gametes and embryos from fertilization through day 5/6 of development in vitro. This device can be used for transfer of embryos to the uterus.	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.
pH (under 5% CO_2)	Same as predicate	7.25-7.54
Osmolality	Same as predicate	260-270 mOsm/kg
Formulation	Same ingredients as in predicate	36 ingredients
The subject and predicate devices have the same indication – culture of embryos from fertilization to blastulation. The subject device is also indicated for embryo transfer, while predicate device does not have this indication. This difference does not represent a new intended use as both devices are intended for in vitro fertilization (IVF) procedures that require transfer of embryos into the uterus, and is in-line with other devices cleared under the same regulation/product code that are used for both culture and embryo transfer. The subject and predicate devices are composed of the same ingredients and have the same pH and osmolality specifications. The only difference is that the concentrations of certain ingredients are modified in the subject device. The difference noted is minor and does not raise different questions of safety and effectiveness. In addition to pH and osmolality, the acceptance criteria for mouse embryo assay (MEA), human sperm survival assay (HSSA), endotoxin testing, and sterility testing for the subject device are same to those of the predicate device.		

VIII. Summary of Non-clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate device:

- pH
- Osmolality
- Aseptic Processing Validation testing per ISO 13408-1:2008 and ISO 13408-2:2003
- Sterility testing per USP <71>

- Endotoxin testing per USP <85>
- Mouse embryo assay (MEA)

  One-cell mouse embryos were exposed to subject devices and cultured at 37°C in an atmosphere containing 5% CO_2. The percent of embryos developed to the expanded blastocyst stage at 96 hours were assessed in comparison with the control group.
- Biocompatibility studies, as follows:
  - Cytotoxicity testing per 10993-5:2009
  - Guinea Pig Maximization Sensitization testing per ISO 10993-10:2010
  - Intracutaneous Reactivity testing per ISO 10993-10:2010
- Shelf-life studies (real-time and accelerated) were conducted to ensure that the following acceptance criteria for product characteristics are met at time zero and the end of shelf-life:
  - pH – See table above
  - Osmolality – See table above
  - 1-cell MEA – ≥80% developed to the blastocyst stage at 96 hours
  - HSSA – ≥70% of original motility at 24 hours
  - Endotoxin – ≤0.25 EU/ml (LAL)
  - Sterility – No microbiological growth
- Stability testing was conducted to ensure that acceptance criteria for the product characteristics are met after repeated opening/closing of bottles for four weeks if handled appropriately.

XI. Conclusion:

The subject and predicate devices have the same intended use. Although there is a difference in formulation between the subject and predicate devices, this difference does not raise different questions of safety or effectiveness. The performance data also demonstrate that the subject device is substantially equivalent to the predicate device.