March 2, 2018

Origio a/s
Tove Kjaer
Director, Corporate Regulatory Affairs
Knardrupvej 2
2760 Måløv
Denmark

Re: K173624
Trade/Device Name: ORIGIO® Handling™ without phenol red (Cat. No. 8310), ORIGIO® Handling™ with phenol red (Cat. No. 8311)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: Class II
Product Code: MQL
Dated: November 28, 2017
Received: December 4, 2017

Dear Tove Kjaer:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Viviano -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173624

Device Name
ORIGIO® Handling™ (Cat. No. 8310)
ORIGIO® Handling™ with phenol red (Cat. No. 8311)

Indications for Use *(Describe)*

ORIGIO® Handling™ is intended for in vitro procedures involving handling and micromanipulation of gametes and embryos outside the CO2 incubator.

Indication includes oocyte retrieval including follicle flushing, gamete (oocyte/sperm) and embryo washing, and micromanipulation procedures including Intra Cytoplasmic Sperm Injection (ICSI), assisted hatching and trophectoderm biopsy.

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.

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K173624 – ORIGIO® Handling™

510(k) SUMMARY

Submitted By: ORIGIO a/s
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Denmark

Contact Person: Tove Kjær
Director Corporate Regulatory Affairs
ORIGIO a/s

Phone: +45 4679 0220
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Date Prepared: March 1, 2018

Device Identification:

Trade name: ORIGIO® Handling™ without phenol red (Cat. No. 8310)
ORIGIO® Handling™ with phenol red (Cat. No. 8311)

Common name: Embryo Culture Media

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

Product code: MQL (Media, Reproductive)

Regulatory class: II

Predicate Device:

Quinn's Advantage Medium with HEPES (K002836). This predicate device has not been subject to any design related recalls.

Device Description:

ORIGIO® Handling™ is a non-viscous, ready-to-use solution providing supporting conditions for human gametes and embryos during in vitro Assisted Reproduction Technology (ART) procedures taking place outside the CO_2 incubator. This product can also be used for oocyte retrieval including follicle flushing.

ORIGIO® Handling™ consists of amino acids, glucose, physiological salts, calcium lactate, sodium pyruvate, vitamins, sodium bicarbonate MOPS/HEPES, human serum albumin, and gentamicin sulfate. This product is supplied with phenol red (Cat. No. 8311) or without phenol red (Cat. No. 8310).

ORIGIO® Handling™ is a single-use device that is aseptically filled into sterilized bottles (60 and 125 ml) and has a sterility assurance level (SAL) of 10^{-3}. The product is stored at 2-8℃, and if not warmed, the product can be used for up to seven days after bottle opening. Prior

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to use, ORIGIO® Handling™ must be pre-warmed to 37℃, except for sperm washing procedures where the product is pre-warmed to room temperature before use.

Indication for Use:

ORIGIO® Handling™ is intended for in vitro procedures involving handling and micromanipulation of gametes and embryos outside the CO_2 incubator.

Indication includes oocyte retrieval including follicle flushing, gamete (oocyte/sperm) and embryo washing, and micromanipulation procedures including Intra Cytoplasmic Sperm Injection (ICSI), assisted hatching and trophectoderm biopsy.

Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices:

Device/Predicate Device(s)	Subject device (K173624)	Predicate device (K002836)
Indications for Use	ORIGIO® Handling™ is intended for in vitro procedures involving handling and micromanipulation of gametes and embryos outside the CO_2 incubator. Indication includes oocyte retrieval including follicle flushing, gamete (oocyte/sperm) and embryo washing, and micromanipulation procedures including Intra Cytoplasmic Sperm Injection (ICSI), assisted hatching, and trophectoderm biopsy.	Quinn's Advantage Medium with HEPES is for in vitro procedures involving manipulations of gametes and embryos not requiring the use of a CO_2 incubator.
pH	7.3-7.5	7.0-7.4
Osmolality	277-293 mOsm/kg	257-273 mOsm/kg
Formulation	Comparable	

The indications for use for the subject and predicate devices are not identical as the subject device has specific indications for oocyte retrieval, gamete and embryo washing, and micromanipulation procedures including ICSI, assisted hatching, and trophectoderm biopsy, whereas the predicate indication does not include these specific uses. These uses do not represent a new intended use as they fall within the scope of media used for handling and manipulation of gametes and embryos outside of a CO_2 incubator.

In regards to device technical characteristics, there are minor differences pH, osmolality and formulations between the subject and predicate devices. These differences do not raise different questions of safety and effectiveness.

Summary of Non-Clinical Performance Testing:

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

- pH testing per USP <791>
- Osmolality per USP <785>
- Aseptic Processing Validation study per ISO 13408-2:2011

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- 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% CO2. The percent of embryos developed to the expanded blastocyst stage within 96 hours were assessed in comparison with the control group.
- Human Sperm Survival Assay (HSSA)

  One part sperm suspension and five parts medium are mixed and sperm motility assessed using a Computer Assisted Sperm Analyzer (CASA) at time zero (control) and 6 hours after incubation at room temperature. The percentage of motile sperm at 6 hours is compared with the control.
- Biocompatibility studies, as follows:
  * Cytotoxicity testing per 10993-5:2009
  * Local Lymph Node Assay (LLNA) testing per ISO 10993-10:2010
  * Vaginal Irritation testing per ISO 10993-10:2010
- Shelf-life studies (real-time) were conducted to ensure that the following product specifications are met at time zero and the end of the XX shelf-life.
  * pH – See tables above
  * Osmolality – See tables above
  * 1-cell MEA – ≥80% developed to the blastocyst stage at 96 hours
  * HSSA – Sperm motility ≥80% of control after incubation for 6 hours
  * Endotoxin – ≤0.1 EU/ml (LAL)
  * Sterility – No microbiological growth

Conclusion

The subject and predicate devices have the same intended use and comparable technological characteristics. The differences in technological characteristics between subject and predicate devices do not raise different questions of safety and effectiveness. The performance data demonstrate that the subject device is substantially equivalent to the predicate device.