DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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July 22, 2016

ORIGIO a/s
Tove Kjaer
Director Corporate Requlatory Affairs
Knardrupvej 2
2760 Måløv
Denmark

Re: K153267
Trade/Device Name: ORIGIO® Sperm Wash, ORIGIO® Gradient™ 100, ORIGIO® Gradient™ 90 and ORIGIO® Gradient™ 40/80
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive media and supplements
Regulatory Class: II
Product Code: MQL
Dated: June 21, 2016
Received: June 23, 2016

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.

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,

Joyce M. Whang -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)*

Device Name
ORIGIO® Sperm Wash, ORIGIO® Gradient™ 100, ORIGIO® Gradient™ 90 and ORIGIO® Gradient™ 40/80

Indications for Use *(Describe)*
ORIGIO® Sperm Wash is intended for washing of spermatozoa, the isolation of motile viable sperm by swim-up method, dilution of ORIGIO gradients, and holding sperm for IUI procedure

ORIGIO® Gradient™ 100, ORIGIO® Gradient™ 90 and ORIGIO® Gradient™ 40/80 are for separation of motile sperm from the ejaculate by the density gradient method.

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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510(k) SUMMARY

510(k) Number: K153267

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Contact person: Tove Kjær
Director Corporate Regulatory Affairs
ORIGIO a/s
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Date Prepared: July 21, 2016

Device Identification:

Trade name: ORIGIO® Gradient™ 100 (Cat. No. 8400)
ORIGIO® Gradient™ 90 (Cat, No. 8401)
ORIGIO® Gradient™ 40/80 (Cat, No. 8402)
ORIGIO® Sperm Wash (Cat, No. 8405)

Common name: Density Gradient and Sperm Wash

Classification name: Reproductive media and supplements (21 CFR 884.6180, Product Code MQL)

Predicate Devices:

SupraSperm™ System (K003404) from ORIGIO is the predicate device for ORIGIO® Gradient™ devices

Sperm Preparation Medium (K991332) from ORIGIO is the predicate device for ORIGIO® Sperm Wash.

Device Description:

ORIGIO® Sperm Wash and ORIGIO® Gradient™ devices are for separation of motile sperm from semen and handling of sperm. These devices are based on the same formulation, but differ in the content of Human Serum Albumin (HSA), NaCl, bicarbonate, and silane silica. The silane silica generates the density, thus it is an ingredient in the ORIGIO® Gradient™ devices only and is not present in ORIGIO® Sperm Wash. All subject devices, except ORIGIO® Gradient™ 100, contain gentamicin and HSA.

The subject devices are aseptically filtered, colorless solutions. ORIGIO® Gradient™ devices are viscous while ORIGIO® Sperm Wash is non-viscous. They are contained in transparent polyethylene terephthalate glycol (PETG) bottles with high density polyethylene (HDPE) closures, available in card board boxes, individually labeled and with instruction for use provided as a package insert. The subject devices are quality control tested for the following specifications:

Criteria	ORIGIO® Sperm Wash	ORIGIO® Gradient™			
		40	80	90	100
pH	7.95-8.495				
Osmolality (mOsm/kg)	272-288	317-333	297-313		
Density (g/ml)	N/A	1.048-1.062	1.098-1.112	1.105-1.119	1.123-1.137
Human Sperm Survival Test	≥80% of control				
Endotoxin (EU/ml)	≤0.15	≤0.8			
Sterility	No growth ($SAL10^{-3}$)				
HSA concentration (mg/ml)	10	5	5	5	N/A

Indications for Use:

ORIGIO®Sperm Wash is intended for washing of spermatozoa, the isolation of motile viable sperm by swim-up method, dilution of ORIGIO® gradients, and holding sperm for IUI procedure.

ORIGIO® Gradient™ 100, ORIGIO® Gradient™ 90 and ORIGIO® Gradient™ 40/80 are for the separation of motile sperm from the ejaculate by the density gradient method.

Performance and Safety Data:

Product Specifications

The bench testing demonstrated that the subject devices met all product specifications.

Biocompatibility

Since ORIGIO® Sperm Wash can also be used for IUI (Intrauterine insemination), it may have direct contact with the uterus (patient). In accordance with ISO 10993-1:2009, the cytotoxicity, sensitization and irritation tests have been conducted on this device and the results demonstrate that ORIGIO® Sperm Wash is safe.

Sterilization Validation

The subject devices are manufactured by aseptically filtration that was validated in accordance with EN/ISO 13408-2:2011. These products have a sterility assurance level (SAL) of 10^{-3}.

Shelf-Life

The shelf-life study covering all product specifications has been conducted on the subject devices. The results demonstrate that Gradient™ 100 has a 20-week shelf-life whereas the other subject devices have a 36-week shelf-life in unopened bottle under recommended storage conditions. In addition, all subject devices are stable for four weeks under recommended storage conditions after the bottles have been opened.

Effectiveness of Separation of Motile Sperm

The sperm separated using subject devices were evaluated for motility, morphology, viability, purity and integrity in comparison with predicate and other cleared devices. The results demonstrate that the subject and predicate devices have comparable performance.

Predicate Device Comparison:

ORIGIO® Sperm Wash

ORIGIO® Sperm Wash and its predicate device have the same intended use. The subject device is different from predicate devices in pH; however, this difference is commonly seen in reproductive media. Regarding formulation, there are following differences between the subject and predicate devices:

- Citrate is present in ORIGIO® Sperm Wash at higher concentration compared to the predicate device. However, citrate is a natural component in semen and present in much higher concentration than in ORIGIO® Sperm Wash.
- Sodium bicarbonate is present in ORIGIO® Sperm Wash at lower concentration compared to the predicate device, but within the range of other cleared sperm wash media.
- Unlike the predicate device, Synthetic Serum Replacement (SSR) is not present in ORIGIO® Sperm Wash. However, SSR is also absent in other cleared media intended for sperm handling. Therefore, absence of SSR is not considered detrimental for the sperm cells.
- HSA concentration has been increased from 5 mg/ml in the predicate device to 10 mg/ml in ORIGIO® Sperm Wash. However, the level of HSA in ORIGIO® Sperm Wash is still much lower than physiological level.
- Taurine is present in ORIGIO® Sperm Wash but absent in the predicate device. However, taurine which is widely used in ART media, including cleared devices with similar indication.

Taken together, the differences do not raise new types of questions. Performance data shows that ORIGIO® Sperm Wash is as safe and effective as the predicate device. Therefore, ORIGIO® Sperm Wash is substantially equivalent to the predicate device in terms of safety and effectiveness.

ORIGIO® Gradient™ devices

ORIGIO® Gradient™ devices and their predicate device have the same intended use. Gradient™ devices are different from the predicate device in pH and osmolality; however, these differences are commonly seen in reproductive media. Regarding formulation, there are following differences between the subject and predicate devices:

- ORIGIO® Gradient™ 40 contains a slightly higher concentration of NaCl, as compared to the predicate device, in order to adjust the medium to a slightly higher osmolality. However, the NaCl concentration used is still within the physiological range of semen.
- Taurine is present in ORIGIO® Gradient™ devices but absent in the predicate device. However, taurine is widely used in ART media, including cleared devices with similar indication.
- HSA concentration has been increased to 5 mg/ml in ORIGIO® Gradient™ 40, 80 and 90. This concentration is within the normal range of cleared media intended for sperm.

- Citrate is present in ORIGIO® Gradient™ devices at higher concentration compared to the predicate device. However, citrate is a natural component in semen and present in much higher concentration than in ORIGIO® Gradient™ devices.
- ORIGIO® Gradient™ devices do not contain SSR or phenol red compared to the predicate device. However, absence of SSR and phenol red are commonly seen in cleared media intended for sperm and therefore, it is not considered detrimental for the sperm cells.

Taken together, the differences do not raise new types of questions. Performance data shows that ORIGIO® Gradient™ devices are as safe and effective as the predicate device. Therefore, ORIGIO® Gradient™ devices are substantially equivalent to the predicate device in terms of safety and effectiveness.