DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 04, 2015

Vitrolife A/S
Belinda Dueholm
Regulatory Affairs Specialist
Jens Juuls Vej 20
DK-8260 Viby J
Denmark

Re: K150961
Trade/Device Name: Embryoslide Culture Dish
Regulation Number: 21 CFR 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: Class II
Product Code: MQK
Dated: October 2, 2015
Received: October 7, 2015

Dear Belinda Dueholm,

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,

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)*
K150961

Device Name

EmbryoSlide culture dish

Indications for Use *(Describe)*

The EmbryoSlide culture dish is intended for preparing, storing, and transferring human embryos. It is intended to be used only with the EmbryoScope device.

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
for the Vitrolife A/S
EmbryoSlide Culture Dish

(per 21CFR 807.92(c))

1. SUBMITTER/510(K) HOLDER

Vitrolife A/S
Jens Juuls Vej 20
DK-8260 Viby J
Denmark

Contact Person: Ms. Belinda Dueholm
Telephone: +45 7221 7900 (main) +45 2076 3707 (direct)

Date Prepared: April 1, 2015

2. DEVICE NAME

Proprietary Name: EmbryoSlide culture dish
Common/Usual Name: IVF Incubator and Accessories
Classification Name: Assisted Reproduction Labware (21 CFR 884.6160)

3. PREDICATE AND REFERENCE DEVICES

- K092183, Vitrolife A/S EmbryoSlide culture dish (Predicate device)
- K070047, Nunc IVF 4-Well Dish (Reference device)

4. DEVICE DESCRIPTION

The Vitrolife A/S EmbryoSlide culture dish is intended for preparing, storing, and transferring human embryos. The Vitrolife A/S EmbryoSlide culture dish is intended to be used with the EmbryoScope device that was previously cleared via K092183, K111715 and K133712. A previous version of the EmbryoSlide culture dish was cleared via K092183. Minor modifications have been made to the original EmbryoSlide culture dish as described below.

The proposed EmbryoSlide culture dish contains two types of wells: wells which are only used

for rinsing and handling the embryos before or after incubation and wells in which the embryos reside during incubation. The original EmbryoSlide culture dish included only wells for which the embryos reside during incubation.

This EmbryoSlide culture dish fits exactly on the culture dish holder in the incubator and holds a maximum of 12 embryos in separate micro wells. As with the original EmbryoSlide culture dish, the proposed EmbryoSlide culture dish contains a large oil reservoir with 12 wells for the incubation of 12 individual embryos. Each well has a volume of 25 µl. Inside each well there is a central depression where the embryo rests. The well has a diameter of approximately 250 µm.

As described above, the proposed EmbryoSlide culture dish includes 4 special wells, two at each end of the culture dish that are intended for rinsing and general handling of the embryos either before or after incubation. Like the other wells, these handling/rinsing wells are designed to hold a volume of 25µl.

5. INTENDED USE

The EmbryoSlide culture dish is intended for preparing, storing, and transferring human embryos. It is intended to be used only with the EmbryoScope device.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The subject and predicate device have the following differences in technological characteristics: addition of rinsing wells to the culture dish, changes to the dimensions of the dish, the use of a different polystyrene formulation, and modifications to the device packaging. The differences in technological characteristics do not raise different questions of safety and effectiveness.

7. PERFORMANCE TESTING

The EmbryoSlide® culture dish is tested per LOT for performance by 1-cell Mouse Embryo Assay (MEA) testing, which requires a blastocyst rate of at least 80% at 96 hours for adequate performance.

The EmbryoSlide® culture dish was tested for *in vitro* cytotoxicity in cultured mammalian cells. The test was performed in accordance with the *United States Pharmacopeia (USP)* <87> and the ISO 10993-5 guidelines. Based on the results, EmbryoSlide® culture dish passes the requirements of ISO 10993-5 and USP <87> as the cytotoxicity grade was ≤ 2.

The EmbryoSlide® culture dish is tested per LOT for bacterial endotoxins using the kinetic chromogenic method. The test of the undiluted extract (the test solution) was performed in

accordance with the US Pharmacopeia <85> and <161>. The test solution contained less than 20 EU/device, which is the maximum, as stated in the USP <85> and <161>.

The EmbryoSlide® culture dish devices are sterilized under controlled conditions via electron beam radiation. The minimum dose has been validated according to ISO 11737 to a sterility assurance level of 10^{-6}.

Shelf life was determined through an accelerated aging study evaluating the package integrity and MEA.

Conclusion

The performance testing demonstrates that the subject device is substantially equivalent to the proposed predicate device.