March 11, 2022

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

Re: K213869
Trade/Device Name: EmbryoSlide+ ic8 dish
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted Reproduction Labware
Regulatory Class: II
Product Code: MQK
Dated: December 7, 2021
Received: December 13, 2021

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213869

Device Name
EmbryoSlide+ ic8 dish

Indications for Use *(Describe)*
The EmbryoSlide+ ic8 dish is intended for culturing, handling and preparation for transfer of human embryos. The EmbryoSlide+ ic8 dish must be used together with the EmbryoScope+ incubator.

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.

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510(k) Summary
K213869
EmbryoSlide+ ic8 dish

1. SUBMITTER INFORMATION

Submitter: Vitrolife A/S
Jens Juuls Vej 20
8260 Viby J
Denmark

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

2. DATE PREPARED

March 10, 2021

3. DEVICE INFORMATION

Device Name	EmbryoSlide+ ic8 dish
Common Name	Culture dish
Regulation Number	21 CFR 884.6160
Regulation Name	Assisted Reproduction Labware
Product Code	MQK (Labware, Assisted Reproduction)
Regulatory Class	II

4. PREDICATE DEVICE

EmbryoSlide+ culture dish, K173264, (Vitrolife A/S).

The predicate device has not been subject to a design-related recall.

5. DEVICE DESCRIPTION

The EmbryoSlide+ ic8 dish is single use, sterile for embryo culture, handling, and preparation for transfer during assisted reproduction technology procedures. The EmbryoSlide+ ic8 dish is equipped with barcode label area for unique identification of the culture dish, and a small area which can be used for manual writing.

The EmbryoSlide+ ic8 dish has eight culture wells. Each well holds a single embryo in 20µL of culture medium.

In addition, four rinsing wells are available, each rinsing well holding 25-30µL medium. The culture area of the dish, comprising both the culture wells and rinsing wells, must be covered with 1.6mL culture oil overlay to minimize osmolarity changes during culture in a dry environment.

The EmbryoSlide+ ic8 dish has the following device specifications:

Parameter	Specification
Appearance	Good clarity with no apparent flaw
Sterility	SAL 10^{-6} (based on process validation data and package integrity testing).
Endotoxin Testing (USP <85>)	≤ 20 EU/device
Mouse Embryo Assay (MEA)	1-cell MEA: ≥80% embryos developed to blastocyst at 96 hours
Cytotoxicity (ISO 10993-5, USP <87>)	Non-cytotoxic

6. INDICATIONS FOR USE

The EmbryoSlide+ ic8 dish is intended for culturing, handling and preparation for transfer of human embryos. The EmbryoSlide+ ic8 dish must be used together with the EmbryoScope+ incubator.

7. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS OF THE SUBJECT AND PREDICATE DEVICE

The table below compares the intended use and technological characteristics of the subject and predicate device.

Attribute	Subject Device EmbryoSlide+ ic8 dish K213869	Predicate Device EmbryoSlide Culture Dish 173264	Differences
Indications for use	The EmbryoSlide+ ic8 dish is intended for culturing, handling and preparation for transfer of human embryos. The EmbryoSlide+ ic8 dish must be used together with the EmbryoScope+ incubator.	The EmbryoSlide+ culture dish is intended for preparing, storing, and transferring human embryos. The EmbryoSlide+ culture dish must be used together with the EmbryoScope+ incubator.	The indications for the subject and predicate devices are similar. Both the predicate and subject devices are indicated for culturing of embryos for transfer.
General design	Optically clear culture dish with a lid	Optically clear culture dish with a lid	Same
Material	Polystyrene	Polystyrene	Same
Number of culture wells for individual embryo incubation	8	16	**Different:** Different number of wells are present in the subject and predicate devices. Differences in well numbers do not raise different questions of safety and effectiveness.
Traceability/ID	Individually numbered wells	Individually numbered wells	Same
Number of rinsing wells	4	4	Same
Barcode label	Area for label (barcode)	Area for label (barcode)	Same

As stated in the table, the subject and predicate devices have similar indications for use statements and have the same intended use (i.e., culturing embryos for transfer). The subject and predicate devices have differences in their technological characteristics (i.e., different number of culture wells). The differences in technological characteristics do not raise different questions of safety and effectiveness.

8. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following non-clinical performance testing has been conducted on the EmbryoSlide+ ic8 dish to support substantial equivalence to the predicate device:

- Radiation sterilization and validation testing per ISO 11137-1:2006/A2013, ISO 11137-2:2013, ISO 11737-1:2018, and ISO 11737-2:2019.
- Transportation simulation testing per ASTM D4169-16
- Package integrity testing after accelerated aging per ASTM F1908-16:
  - Bubble test per ASTM F2096-11
  - Peel strength testing ASTM F88/F88M-09
- Endotoxin testing per USP <85>. The testing demonstrated that the device met the specification of ≤20 EU/device.
- Mouse embryo assay (MEA) per the 2021 FDA guidance document “Mouse Embryo

Assay for Assisted Reproduction Technology Devices:"

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 within 96 hours were assessed in comparison with the control group. The testing demonstrated that the device met acceptance criterion of "1-cell MEA ≥80% embryos developed to blastocyst in 96 hours."

- Shelf-life testing (accelerated aging) per ASTM F1980:2016. The following testing was conducted:
  - Endotoxin testing per USP <85>
  - MEA per the 2021 FDA guidance document ""Mouse Embryo Assay for Assisted Reproduction Technology Devices"

9. CONCLUSIONS

The results of the performance testing described above demonstrate that the subject media products are as safe and effective as the predicate devices and support a determination of substantial equivalence.