DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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July 20, 2015

HertART ApS
Göran Mellbin
Director of Quality and Operations
Gustaf Werners gata 2
V. Frölunda, SE-421 32
Sweden

Re: K150756
Trade/Device Name: Micro well group culture dish, 9-well
Micro well group culture dish, 16-well
Regulation Number: 21 CFR§ 884.6160
Regulation Name: Assisted reproduction labware
Regulatory Class: II
Product Code: MQK
Dated: May 29, 2015
Received: May 29, 2015

Dear Göran Mellbin,

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,

Herbert P. Lerner -S

for Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Device 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)*
K150756

Device Name
Micro well group culture dish, 9-well
Micro well group culture dish, 16-well

Indications for Use *(Describe)*
For in-vitro fertilisation, handling and embryo culture. It may be used for the culturing of embryos using drop culture

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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HertART at the beginning of life

Chapter 5: 510(k) Summary

COMPANY

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Date of Summary:	July 18, 2015

DEVICE

Trade names:	Micro well group culture dish, 9-well Micro well group culture dish, 16-well
Common name:	IVF Dishes
Classification name:	Assisted Reproduction Labware, 21 CFR884.6160, Code MQK

PREDICATE DEVICE

Proposed Device:
Micro well group culture dish, 9-well

Predicate Device:

Proprietary Name:	Vitrolife Micro Droplet Culture Dish
Common Name:	IVF Dish
Manufacturer:	HertART ApS
510(k) Number:	K123641

Proposed Device:
Micro well group culture dish, 16-well

Predicate Device:

Proprietary Name:	Vitrolife Micro Droplet Culture Dish
Common Name:	IVF Dish
Manufacturer:	HertART ApS

Chapter 5: 510(k) Summary

510(k) Number: K123641

DESCRIPTION OF DEVICE

The Micro well group culture dishes are injection molded and disposable. The dishes are round and supplied with a lid. The dishes holds 9 small wells respectively 16 small wells.
The polymers used for the dishes are virgin crystal grade polystyrene, which has successfully passed 1- cell embryotoxicity test. The dishes are packed 1 unit in a sleeve, 10 sleeves in a case as defined below:

Trade Name	Configuration	Packaging
Micro well group culture dish, 9-well	Round dish with lid. Diameter 40 mm x12 mm 9 round wells in dish. Culture area 0.07 mm^2 per well.	1 unit per sleeve 10 units per case
Micro well group culture dish, 16-well	Round dish with lid. Diameter 40 mm x12 mm 16 round wells in dish. Culture area 0.07 mm^2 per well.	1 unit per sleeve 10 units per case

The dishes are terminally sterilized by irradiation to achieve a SAL of 10^{-6}.
The dishes are non-pyrogenic as tested by LAL, and non-embryotoxic as tested by one cell Mouse Embryo Assay (MEA).
The Dishes are single use devices.

INTENDED USE

The medical condition to be treated is infertility. The target group is couples incapable of getting fertile by normal sexual intercourse.
It is the Doctor who takes the clinical decision on who should receive fertility treatment, named In Vitro Fertilization (IVF). For this procedure disposable plastic dishes are routinely used for sampling, handling, culturing and purification of gemetes for In Vitro Fertilization.

Micro well group culture dish, 9-well:
For in vitro fertilisation, handling and embryo culture. It may be used for the culturing of embryos using drop culture

Micro well group culture dish, 16-well:
For in vitro fertilisation, handling and embryo culture. It may be used for the culturing of embryos using drop culture

The additional common claims are

- Devices are sterile (SAL 10^{-6})
- Devices are non-embryotoxic (Embryo safe)
- Devices are non pyrogenic
- Devices are single-use
- Devices are for 'Professionals' only (R_x)

Chapter 5: 510(k) Summary

Overview: Comparison between proposed devices and predicate devices

	Proposed Device **Micro well group culture dish, 9-well**	***Predicate Device*** **Vitrolife Micro Droplet Culture Dish 510(k) K123641**	***Differences***
Device	Round dish with 9 round wells	Square dish with 12 round wells	Proposed device is round with 9 round wells compared to square dish with 12 round wells in predicate device
Indication for use / intended use	For in vitro fertilisation, handling and embryo culture. It may be used for the culturing of embryos using drop culture.	Intended for IVF. It may be used with sperm and the culturing of embryos using drop culture.	None, As both predicate and proposed dish may be using drop culture and co-culture having separate wells to hold the cells. Both devices can be used with sperm, but due to the design it is unlikely that clincs will use the Micro well group culture dish for this.
Material	Virgin Polystyrene,	Virgin Polystyrene,	none
Dimensions	Dish with lid: Diameter 40 mm x 12mm	Dish with lid: 65,96 mm x 65,96 mm x 13,20 mm	Proposed dish is round and a bit smaller than the square predicate device
Design features	The basic design is a round culture dish with nine small wells/grooves (culture area per well 0.07 mm^2) situated in the center of the dish for easy microscopy / imaging. Each cavity has a volume of approximately 0.02 µL and is only intended to keep each embryo in a fixed place so that it can be individually evaluated during the culture. The total volume to be used will depend on how the clinic uses the dish and may vary in size from 50	The basic design is a square culture dish with twelve small wells (volume 12.5 microliter, holding standing drops up to 50 microliter). The micro-wells are placed with a-numerical ID in a rectangular well format to allow easy identification during microscopy. The height of a well is approximately 0.95 mm at the bottom with sides sloping to approximately 4.3 mm at the top. There will typically be one separated media-drop in	The predicate device has 12 wells (12.5 µL) distributed in an array across large part of the base of the dish, while the proposed device has 9 wells /grooves (0.02 µL) situated in an array at the center of the dish for easy microscopy/imaging

	µL to 150 µL depending on the time and number of embryos cultured. The micro-wells are placed with α-numerical ID in a rectangular well format to allow easy identification during microscopy. The lids are designed for aseptic manipulation and consistent venting to maintain proper humidification.	each well, this is, however, not linked to if the customer decides to place several embryos in each well (co-culture) or only one embryo (single embryo culture). The lids are designed for aseptic manipulation and consistent venting to maintain proper humidification. A patient ID area not covering the lid.	
Packaging	1 dish per sleeve 10 dishes per case	5 dishes per sleeve, 400 dishes per case	Proposed device is single packed in sleeve
Performance testing	Sterile (SAL 10^{-6}), Non-pyrogenic by Limulus Amebocyte Lysate assay (LAL of < 0,25 EU/Device) Non-embryotoxic tested by Mouse Embryotoxicity assay (MEA) 1-cell method.	Sterile (SAL 10^{-6}), Non-pyrogenic by Limulus Amebocyte Lysate assay (LAL of < 0,25 EU/Device) Non-embryotoxic tested by Mouse Embryotoxicity assay (MEA) 1-cell method.	none
Discussion	Predicate device is square and has 12 wells placed in an array across the base of the dish. The proposed device is round and has 9 wells/grooves placed in an array at the center of the dish. The design of the proposed device facilitates the simultainiously imaging of the embryos in the multiple wells/grooves. The differences do not impact the use of the identified predicate device to support the proposed device, as they do not raise any new types of safety or effectiveness questions. Therefore, the subject is substantially equivalent to the predicate device.		

Chapter 5: 510(k) Summary

	Proposed Device **Micro well group culture dish, 16-well**	***Predicate Device*** ***Vitrolife*** ***Micro Droplet Culture Dish*** ***510(k) K123641***	***Differences***
Device	Round dish with 16 round wells	Square dish with 12 round wells	Proposed device is round with 16 round wells compared to square dish with 12 round wells in predicate device
Indication for use / intended use	For in vitro fertilisation, handling and embryo culture. It may be used for the culturing of embryos using drop culture.	Intended for IVF. It may be used with sperm and the culturing of embryos using drop culture.	None, As both predicate and proposed dish may be using drop culture and co-culture having separate wells to hold the cells. Both devices can be used with sperm, but due to the design it is unlikely that clincs will use the Micro well group culture dish for this.
Material	Virgin Polystyrene,	Virgin Polystyrene,	none
Dimensions	Dish with lid: Diameter 40 mm x 12mm	Dish with lid: 65,96 mm x 65,96 mm x 13,20 mm	Proposed dish is round and a bit smaller than the square predicate device
Design features	The basic design is a round culture dish with nine small wells/grooves (culture area per well 0.07 mm^2) situated in the center of the dish for easy microscopy / imaging. Each cavity has a volume of approximately 0.02 µL and is only intended to keep each embryo in a fixed place so that it can be individually evaluated	The basic design is a square culture dish with twelve small wells (volume 12.5 microliter, holding standing drops up to 50 microliter). The micro-wells are placed with a-numerical ID in a rectangular well format to allow easy identification during microscopy. The height of a well is approximately 0.95 mm at	The predicate device has 16 wells (12.5 µL) distributed in an array across large part of the base of the dish, while the proposed device has 9 wells /grooves (0.02 µL) situated in an array at the center of the dish for easy microscopy/imaging

	during the culture. The total volume to be used will depend on how the clinic uses the dish and may vary in size from 50 µL to 150 µL depending on the time and number of embryos cultured. The micro-wells are placed with a-numerical ID in a rectangular well format to allow easy identification during microscopy. The lids are designed for aseptic manipulation and consistent venting to maintain proper humidification.	the bottom with sides sloping to approximately 4.3 mm at the top. There will typically be one separated media-drop in each well, this is, however, not linked to if the customer decides to place several embryos in each well (co-culture) or only one embryo (single embryo culture). The lids are designed for aseptic manipulation and consistent venting to maintain proper humidification. A patient ID area not covering the lid.	
Packaging	1 dish per sleeve 10 dishes per case	5 dishes per sleeve, 400 dishes per case	Proposed device is single packed in sleeve
Performance testing	Sterile (SAL 10^{-6}), Non-pyrogenic by Limulus Amebocyte Lysate assay (LAL of < 0,25 EU/mL) Non-embryotoxic tested by Mouse Embryotoxicity assay (MEA) 1-cell method.	Sterile (SAL 10^{-6}), Non-pyrogenic by Limulus Amebocyte Lysate assay (LAL of < 0,25 EU/Device) Non-embryotoxic tested by Mouse Embryotoxicity assay (MEA) 1-cell method.	none
Discussion	Predicate device is square and has 12 wells placed in an array across the base of the dish. The proposed device is round and has 16 wells/grooves placed in an array at the center of the dish. The design of the proposed device facilitates the simultainiously imaging of the embryos in the multiple wells/grooves. The differences do not impact the use of the identified predicate device to support the proposed device, as they do not raise any new types of safety or effectiveness questions. Therefore, the subject is substantially equivalent to the predicate device.		

Signed
Göran Mellbin, Director of Quality&Operations, Chairman of the Board

2015-07-18 (Date)