510(k) Summary

JUL 0 3 2013

COMPANY

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Date of Summary: July 02, 2013

DEVICE NAME

Trade names:	Vitrolife Culture Dish 40 mm Vitrolife Culture Dish 60 mm Vitrolife Micro-droplet Culture Dish Vitrolife 5-well Culture Dish Vitrolife Centre Well Dish Vitrolife ICSI Dish
Common name:	IVF Dishes
Classification name:	Assisted Reproduction Labware
Classification regulation:	21 CFR884.6160
Product code:	MQK
Classification panel:	Obstetrics/Gynecology
Device class:	II

PREDICATE DEVICES

Falcon IVF Round Dish (K991253) for Vitrolife Culture Dish 60 mm & Vitrolife Culture Dish 40 mm

Nunc IVF Multidish 4 Wells Nunclon (K040717) for Vitrolife 5 Well Culture Dish

Nunc IVF ICSI Dish (K090429) for Vitrolife ICSI Dish

Falcon IVF One Well Dish (K991251) for Vitrolife Centre Well Dish

Genx Culture Dish (now marketed as Sun IVF Embryo Corral Dish) (K993881) for Vitrolife Micro Droplet Culture Dish

HertART

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DESCRIPTION OF DEVICE

The HertART disposable dishes are injection molded. The dishes are supplied with a lid. The polymers used for the dishes are virgin crystal grade polystyrene, which has successfully passed the USP class VI test for cytotoxicity, as well as 1-cell embryotoxicity test. The HertART dishes are packed in sleeves of x units in a box for a total of y units, as defined below:

Trade Name	Configuration	Packaging
Vitrolife Culture Dish 60 mm	Round dish with lid: ø63 x 15,15 mm One round well 60 mm in diameter Well Volume: 24,00 mL	10 units per sleeve 540 units per case
Vitrolife Culture Dish 40 mm	Square dish with lid; 65,96 mm x 65,96 mm x 13,20 mm One round well: 40 mm in diameter, Well volume of 12,56 mL	5 units per sleeve 400 units per case
Vitrolife 5-well Culture Dish	Square dish with lid: 65,96 mm x 65,96 mm x 13,20 mm 5 round wells, Well Volume: 1,7 mL	5 units per sleeve 400 units per case
Vitrolife Centre Well Dish	Square dish with lid: 65,96 mm x 65,96 mm x 13,20 mm 1 well, round bottom, oval opening.	5 units per sleeve 400 units per case
Vitrolife ICSI Dish	Square dish with lid: 65,96 mm x 65,96 mm x 11,70 mm 1 square well with rounded corners	5 units per sleeve 400 units per case
Vitrolife Micro-droplet Culture Dish	Square dish with lid: 65,96 mm x 65,96 mm x 13,20 mm 12 round wells holds drops up to 50 µL Well Volume: 12.5 µL	5 units per sleeve 400 units per case

The dishes are terminally sterilized by gamma irradiation to achieve a SAL of 10^{-6}. The dishes are non-pyrogenic as tested by LAL, and non-embryotoxic as tested by 1-cell Mouse Embryo Assay (MEA). The dishes are disposable and intended for single use.

INDICATIONS FOR USE

The Vitrolife Culture Dish 60 mm, Vitrolife Culture Dish 40 mm and Vitrolife Centre Well Dish are intended for IVF, suitable for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures.

The Vitrolife 5 Well Culture Dish is intended for IVF, suitable for preparing, storing, manipulating or transferring human gametes or embryos for in vitro fertilization (IVF), or other in vitro fertilization techniques.

The Vitrolife ICSI Dish is intended for IVF, suitable for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).

The Vitrolife Micro Droplet Culture Dish is intended for IVF. It may be used with sperm and for the culturing of embryos using drop culture.

PREDICATE DEVICE COMPARISON

Parameter	Subject Device – Vitrolife Culture Dish 60 mm	Predicate Device – Falcon IVF Round Dish (K991253)	Differences
Device	Round petri dish with diameter 60 mm	Round petri dish with diameter 60 mm	none
Indication for Use	Intended for IVF, suitable for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures	Intended for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures	none
Material	Virgin Polystyrene, tested for USP Class VI cytotoxicity	Virgin Polystyrene, tested for USP Class VI cytotoxicity	none
Dimensions	Diameter 60 mm	Diameter 60 mm	none
Design features	Round dishes with vented lid. Flat bottom, optically clear surfaces. Surfaces are non-treated	Round dishes with vented lid. Flat bottom, optically clear surfaces. Surfaces are treated for improved wettability	Predicate device is surface treated for increased wettability
Well shape	Well area of 24,07 cm^2	Well area of 24,07 cm^2	none
Well volume	23,00 mL	23,00 mL	none
Discussion	Predicate device uses surface treatment, which is traditionally used for cell culture labware for better cell adhesion. As gametes and embryos do not adhere to surfaces, and since most culture within IVF nowadays is done in drops of media, improved wettability is not a desired product feature for modern IVF procedures. The proposed device uses a more sensitive 1-cell MEA assay compared to the predicate device using a 2-cell MEA in order to improve/ ensure consistency of product performance 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.		

Parameter	Subject Device – Vitrolife Culture Dish 40 mm	Predicate Device – Falcon IVF Round Dish (K991253)	Differences
Device	Square dish with round inner diameter of 40 mm	Round petri dish with diameter 60 mm	Proposed device has square outer geometry and smaller round well
Indication for use	Intended for IVF, suitable for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures.	Intended for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures	None
Material	Virgin Polystyrene, tested for USP Class VI cytotoxicity	Virgin Polystyrene, tested for USP Class VI cytotoxicity	none

Dimensions	Dish Size without lid: 65,96 mm x 65,96 mm x 10,50 mm Dish Size with lid: 65,96 mm x 65,96 mm x 13,20 mm Well diameter: 40 mm	Diameter 60 mm round dish	Proposed device has smaller round diameter
Design features	Square dish with round well. with vented lid. A patient ID area not covered by the lid. Flat bottom, optically clear surfaces. Surfaces are non-treated	Round dishes with vented lid coving all of the dish. Flat bottom, optically clear surfaces. Surfaces are treated for improved wettability	Proposed device has an outer square geometry with ID area. Predicate device is surface treated for increased wettability.
Well shape	Round well area of 12,56 cm^2	Well area of 24,07 cm^2	Proposed device has smaller well area and less mL
Well volume	12,56 mL	23,00 mL	
Discussion	Proposed device has a square outer geometry and a patient ID area. The square outer geometry facilitates the handling and stacking of dishes, while the patient ID area for writing or barcode increases the safety in relation to mix-ups. Predicate device uses surface treatment, which is traditionally used for cell culture labware for better cell adhesion. As gametes and embryos do not adhere to surfaces, and since most culture within IVF nowadays is done in drops of media, improved wettability is not a desired product feature for modern IVF procedures. The proposed device uses a more sensitive 1-cell MEA assay compared to the predicate device using a 2-cell MEA in order to improve/ensure consistency of product performance 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.		

Parameter	**Subject Device – Vitrolife 5 well Culture Dish**	**Predicate Device – Nunc IVF Multidish 4 Wells (K040717)**	**Differences**
Device	Square dish with 5 round wells	Square dish with 4 round wells	Proposed device has 5 wells while predicate device has 4 wells.
Indications for Use	Intended for IVF, suitable for preparing, storing, manipulating or transferring human gametes or embryos for in vitro fertilization (IVF), or other in vitro fertilization techniques	Intended for preparing, storing, manipulating or transferring human gametes or embryos for in vitro fertilization (IVF), or other in vitro fertilization techniques, and cell culture	none
Material	Virgin Polystyrene, tested for USP Class VI cytotoxicity	Virgin Polystyrene, tested for USP Class VI cytotoxicity	none
Dimensions	Base: 65,96 mm x 65,96 mm Dish size with lid: 65,96 mm x 65,96 mm x 13,20 mm	Base: 65,96 mm x 65,96 mm	none
Design features	Square dish with vented lid. A patient ID area not covered by the lid. Flat bottom, optically clear surfaces. Surfaces are non-treated	Square dish with vented lid coving all of the dish. Flat bottom, optically clear surfaces. Product comes both with or without surface treatment for improved wettability	Proposed dish has a patient ID area. Predicate device can come as surface treated for increased wettability

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Well shape	Well area of 1.9 cm^2 Well Volume of 1,7 mL Wells having a ramp along the edge The well diameter is approximately 10.7 mm at the bottom of the well and then quickly expands to a 15,3 mm diameter cylinder. The height is approximately 9.4 mm from the bottom of the well to the rim	Well area of 1.9 cm^2	Proposed device has a ramp along the inner edge of the wells
Discussion	Proposed device has a patient ID area. The square outer geometry facilitates the handling and stacking of dishes, while the patient ID area for writing or barcode increases the safety in relation to mix-ups. Proposed device has a ramp along the inner edge of the wells preventing the embryos from getting stuck in the corners and thereby facilitates the use of the product. Predicate device uses surface treatment, which is traditionally used for cell culture labware for better cell adhesion. As gametes and embryos do not adhere to surfaces, and since most culture within IVF nowadays is done in drops of media, improved wettability is not considered a desired product feature for modern IVF procedures. 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.		

Parameter	**Subject Device – Vitrolife ICSI Dish**	**Predicate Device – Nunc IVF ICSI Dish (K090429)**	**Differences**
Device	Square dish with 1 well with rounded corners	Round dish with 1 round well	Proposed device has square outer geometry and 1 well with rounded corners, while predicate device has round outer geometry and round well
Indication for Use	Intended for IVF, suitable for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).	Intended for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).	none
Material	Virgin Polystyrene, tested for USP Class VI cytotoxicity	Virgin Polystyrene, tested for USP Class VI cytotoxicity	none
Dimensions	Dish Size without lid:65,96 mm x 65,96 mm x 9,00 mm Dish Size with lid: 65,96 mm x 65,96 mm x 11,70 mm The ICSI dish has one large continuous surface with the length (at the bottom of the well) of 50.5 mm and a width of 34.8 mm. The corners are rounded and the total volume is approximately 14.5 mL.	Diameter: 55.77 mm Height without lid: 8.64 mm Height with lid: 9.75 mm	Proposed device is square and wider. Height is comparable.

Design features	The bottom of the dishes is clear and optimal clear. The lid can be handled with one hand while other lab equipment can be handled with the other hand. The dishes can be stacked. A patient ID area not covered by the lid.	The bottom of the dishes is clear and optimal clear. The lid can be handled with one hand while other lab equipment can be handled with the other hand. The dishes can be stacked.	Proposed device has a patient ID area.
Discussion	Proposed device has a patient ID area. The square outer geometry facilitates the handling and stacking of dishes, while the patient ID area for writing or barcode increases the safety in relation to mix-ups. 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.		

Parameter	**Subject Device – Vitrolife Centre Well Dish**	**Predicate Device – Falcon IVF One Well Dish (K991251)**	**Differences**
Device	Square dish with 1 oval well	Round dish with 1 round well	Proposed device has square outer geometry and oval well. Predicate device has round outer geometry and round well
Indication for Use	Intended for IVF, suitable for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures.	Intended for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures	None
Material	Virgin Polystyrene, tested for USP Class VI cytotoxicity	Virgin Polystyrene, tested for USP Class VI cytotoxicity	none
Dimensions	Dish with lid: 65,96 mm x 65,96 mm x 13,20 mm Height without lid: 10,50 mm	Diameter: 55.77 mm Height without lid: 8.64 mm Height with lid: 9.75 mm	Height is comparable
Design features	The dishes have perfectly flat, optically clear surfaces for optimum manipulation and observation of the ova and embryos. The oval well facilitates the handling of the ova and embryos by equipment during microscopy. The lids are designed for aseptic manipulation and consistent venting to maintain proper humidification. The dishes can be stacked. A patient ID area not covered by the lid	The dishes have perfectly flat, optically clear surfaces for optimum manipulation and observation of the ova and embryos. Surfaces are treated for improved wettability. The lids are designed for aseptic manipulation and consistent venting to maintain proper humidification	Proposed device has an oval well while predicate device has a round well. Predicate device is surface treated for increased wettability. Proposed device has a patient ID area

Well shape.	Round bottom with diameter approx. 15.5 mm and a larger oval opening	Round	
Well volume	Well Volume > 2.5 mL	Well volume of 2.5 mL	
Discussion	Proposed device has a patient ID area. The square outer geometry facilitates the handling and stacking of dishes, while the patient ID area for writing or barcode increases the safety in relation to mix-ups. The oval well in proposed device facilitates the handling of the ova and embryos by equipment during microscopy. Predicate device uses surface treatment, which is traditionally used for cell culture labware for better cell adhesion. As gametes and embryos do not adhere to surfaces, and since most culture within IVF nowadays is done in drops of media, improved wettability is not a desired product feature for modern IVF procedures. Proposed device used 1-cell method for MEA testing while predicate device used 2-cell method. There is to day no established standard discriminating between 1-cell or 2-cell method. 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.		

Parameter	**Subject Device – Vitrolife Micro Droplet Culture Dish**	**Predicate Device – Genx Culture Dish (Sun IVF Embryo Corral) (K993881)**	**Differences**
Device	Square dish with 12 round wells	Round dish with 11 round wells	Proposed device has square outer geometry and round walls, while predicate device has round outer geometry and picket-fenced walls
Indication for use / intended use	Intended for IVF. It may be used with sperm and for the culturing of embryos using drop culture.	Intended to be used when culturing tissues and cells. It may be used with sperm and for the culturing of embryos.	Predicate device allows media to flow freely among culturing cells/embryos, however Proposed device allow individual cells/embryos to be cultures in separated drop cultures.
Material	Virgin Polystyrene, tested for USP Class VI cytotoxicity	Polystyrene	Proposed device uses USP Class tested polystyrene
Dimensions	Dish with lid: 65,96 mm x 65,96 mm x 13,20 mm	Outer Diameter: 60 mm	Proposed device has square outer geometry while predicate device has round
Design features	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	The basic design is that of a traditional culture dish. Approx 60 mm round with areas of ½ inch side walls. This dish does not have defined areas for the cell to be confined within. These areas are squares of picket-fenced walls.	Proposed device has a square outer geometry and well areas defined by small solid walls, while predicate device has a round outer geometry and well areas defined by small picket-fenced walls. Proposed device has micro-wells with a-

	approximately 0.95 mm and the diameter is 3.3 mm at 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 covered by the lid.		numerical ID to allow easy identification during microscopy, as well as a separate patient ID area.
Discussion	The square outer geometry of the proposed device facilitates the handling and stacking of dishes, while the patient ID area for writing or barcode increases the safety in relation to mix-ups. Predicate device allows media to flow freely among culturing cells/embryos, while Proposed device allow individual cells/embryos to be cultured in separated drop cultures, which is a routine procedure in many IVF clinics. The alphanumerical ID at each microwell allows easy drop identification during microscopy. 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.		

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 3, 2013

HertART ApS
% Mr. Henrik Dörge
VP Business Development
Korskildelund 6
Greve 2670
DENMARK

Re: K123641
Trade/Device Name: Vitrolife Culture Dish 40 mm, Vitrolife Culture Dish 60 mm, Vitrolife Centre Well Dish, Vitrolife 5 Well Culture Dish, Vitrolife ICSI Dish, and Vitrolife Micro Droplet Culture Dish
Regulation Number: 21 CFR 884.6160
Regulation Name: External uterine contraction monitor and accessories
Regulatory Class: Class II
Product Code: MQK
Dated: May 6, 2013
Received: May 23, 2013

Dear Mr. Dörge:

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 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. 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,

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

Indications for Use Statement

510(k) Number: K123641

Device Name: Vitrolife Culture Dish 40 mm
Vitrolife Culture Dish 60 mm
Vitrolife Centre Well Dish

Indications for Use:

The Vitrolife Culture Dishes are intended for IVF, suitable for use in preparing, storing, manipulating, or transferring human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other reproduction procedures.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123641

Indications for Use Statement

510(k) Number: K123641

Device Name: Vitrolife 5 Well Culture Dish

Indications for Use:

The Vitrolife 5 Well Culture Dish is intended for IVF, suitable for preparing, storing, manipulating or transferring human gametes or embryos for in vitro fertilization (IVF), or other in vitro fertilization techniques.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123641

Indications for Use Statement

510(k) Number: K123641

Device Name: Vitrolife ICSI Dish

Indications for Use:

The Vitrolife ICSI Dish is intended for IVF, suitable for holding oocytes and sperm during fertilization via intracytoplasmic sperm injection (ICSI).

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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2013.07.03 12:47:27 -04'00'

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Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123641

Indications for Use Statement

510(k) Number: K123641

Device Name: Vitrolife Micro Droplet Culture Dish

Indications for Use:

The Vitrolife Micro Droplet Culture Dish is intended for IVF. It may be used with sperm and for the culturing of embryos using drop culture.

Prescription Use ____X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123641