July 23, 2025

Vitrolife Sweden AB
Ann-Cathrine Ericson
RA Manager
Gustaf Werners gata 2
Gothenburg, 421 32
SWEDEN

Re: K243373
Trade/Device Name: Embryo Transfer Catheter (ETC) Assortment:
EmbryoCath Embryo Transfer Catheter - Pre-curved
230 mm (REF 17500);
EmbryoCath Embryo Transfer Catheter - Straight Malleable
180 mm (REF 17501);
EmbryoCath Embryo Transfer Catheter - Straight Malleable
230 mm (REF 17502);
EmbryoCath Stylet - 180 mm (REF 17510);
EmbryoCath Stylet - 230 mm (REF 17511)
Regulation Number: 21 CFR 884.6110
Regulation Name: Assisted Reproduction Catheters
Regulatory Class: II
Product Code: MQF
Dated: June 13, 2025
Received: June 13, 2025

Dear Ann-Cathrine Ericson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Monica D. Garcia, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K243373

Device Name

Embryo Transfer Catheter (ETC) Assortment:
EmbryoCath Embryo Transfer Catheter - Pre-curved 230 mm (REF 17500);
EmbryoCath Embryo Transfer Catheter - Straight Malleable 180 mm (REF 17501);
EmbryoCath Embryo Transfer Catheter - Straight Malleable 230 mm (REF 17502);
EmbryoCath Stylet - 180 mm (REF 17510);
EmbryoCath Stylet - 230 mm (REF 17511)

Indications for Use *(Describe)*

The Embryo Transfer Catheter is intended for introduction of in vitro fertilized embryo(s) into the uterine cavity.

The stylet is intended to be used with Vitrolife´s Embryo Transfer Catheters to assist in uterine access of the guide during an embryo transfer procedure.

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 – K243373

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Date prepared: July 23, 2025

1 Device Identification

Trade Name: Embryo Transfer Catheter (ETC) Assortment:
EmbryoCath Embryo Transfer Catheter - Pre-curved 230 mm (REF 17500);
EmbryoCath Embryo Transfer Catheter - Straight Malleable 180 mm (REF 17501);
EmbryoCath Embryo Transfer Catheter - Straight Malleable 230 mm (REF 17502);
EmbryoCath Stylet - 180 mm (REF 17510);
EmbryoCath Stylet - 230 mm (REF 17511)

Common name: Embryo Transfer Catheters
Regulatory Class: II
Regulation number: 21 CFR 884.6110
Regulation name: Assisted Reproduction Catheters
Product code: MQF (Catheter, Assisted Reproduction)

2. Predicate Device

Kitazato ET Catheters (K162878) manufactured by Kitazato Corporation.

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

3. Device Description

Vitrolife´s Embryo Transfer Catheter (ETC) Assortment consists of three embryo transfer catheters (ETCs), one pre-curved variant (Model 17500, 230 mm) and two straight variants (REFs 17501, 17502) in different lengths (180 mm and 230 mm); and two stylets (Stylets) (REFs 17510, 17511) in different lengths (180 mm and 230 mm). ETC and Stylet are sterile, single-use devices used to deliver in vitro fertilized embryos to the uterine cavity.

Embryo Transfer Catheter consists of:

- A guide, also referred as outer sheath. The guide is used to navigate through the cervix canal. The guide has a distance marking, a stopper and a rounded tip to facilitate proper positioning. The guide is available in two different variants:
    - Pre-curved - stiff

Embryo Transfer Catheter (ETC) Assortment

- Straight - soft and malleable

- A catheter, also referred as inner catheter. The catheter is loaded with the embryo(s) in a small volume of transfer medium and inserted through the guide to gently deposit the embryo(s) into the uterine cavity. The transfer catheter is soft, flexible and approximately 50 mm longer than the guide. The tip of the catheter has an echogenic marking to enable ultrasound guidance.

Embryo Transfer Catheter Stylet consists of:

- A plastic-coated metal wire, which is malleable. The stylet is an accessory that can be used together with Vitrolife's guides to make them stiffer.

The 17500 variant includes a stylet. The 17501 and 17502 variants do not include stylets, but the stylet can be purchased separately.

4. Indications for Use

The Embryo Transfer Catheter is intended for introduction of in vitro fertilized embryo(s) into the uterine cavity.

The stylet is intended to be used with Vitrolife´s Embryo Transfer Catheters to assist in uterine access of the guide during an embryo transfer procedure.

5. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices

Characteristics	**Subject Device K243373**	**Predicate Device K162878**	**Comparison**
Manufacturer	Vitrolife Sweden AB	Kitazato Corporation	N/A
Trade name	Embryo Transfer Catheter (ETC) Assortment: EmbryoCath Embryo Transfer Catheter - Pre-curved 230 mm (REF 17500); EmbryoCath Embryo Transfer Catheter - Straight Malleable 180 mm (REF 17501); EmbryoCath Embryo Transfer Catheter - Straight Malleable 230 mm (REF 17502); EmbryoCath Stylet - 180 mm (REF 17510); EmbryoCath Stylet - 230 mm (REF 17511)	Kitazato ET Catheters	N/A
Indications for use	The Embryo Transfer Catheter is intended for introduction of *in vitro* fertilized embryo(s) into the uterine cavity. The Stylet is intended to be used with Vitrolife´s Embryo Transfer Catheters to assist in uterine access of the guide	The Kitazato ET Catheters are intended for ultrasound guided introduction of embryos into the uterine cavity following in vitro fertilisation. Kitazato ET Catheters are provided in various configurations (Type 1 through Type 5), which	The indications for use statements subject and predicate devices are not identical; however, they have the same intended use (i.e., transfer of embryos into the uterine cavity).

	during an embryo transfer procedure.	consist of the following components: • Transfer Catheter, for delivery of embryos into the uterine cavity; • Guide Catheter, to guide the insertion of the Transfer Catheter and reinforce it during use: • Trial Catheter, used to confirm the curvature of the cervix and if the cervix is passable; • Stylet Sheath, used to increase the strength of the Guide Catheter during insertion.	
Device Components	Embryo transfer catheter, guide and stylet	Transfer catheter, guide catheter, trial catheter, and a stylet sheath	**Different.** The differences in device components do not raise different questions of safety and effectiveness (S&E).
Materials	Straight Guide: Polyethylene (PE), Silicone Pre-curved Guide: Thermoplastic polyurethane (TPU), Silicone Catheter: Thermoplastic polyurethane (TPU), Polyamide (PA 12) Stylet: Stainless steel, Polyamide (PA 12) Luer Connector: PEBA	Catheter/Trial shaft: Polyurethane Guide: Fluoric resin Outer Stiffener: Stainless steel Luer Connector: ABS	**Different.** The differences in device materials do not raise different questions of S&E.
Markings	Distance markings on embryo transfer catheter and guide.	Depth marks on catheter and guide.	Same
Ultrasound visibility	Yes – Echogenic marking	Yes – Echo line for Type3 and Type4.	Same
Single use	Yes	Yes	Same
Dimension	Length: Catheter: 20 cm, 25 cm Guide: 13 cm, 18 cm Stylet: 15 cm, 20 cm OD: Catheter: 1.45 mm Guide: 2.35 mm Stylet: 1.2 mm	Length: Catheter: 18 cm, 23 cm Guide: 14 cm, 19 cm OD: Catheter: 1.55 mm (4.7 Fr) Guide: Unknown Stylet: Unknown	**Different.** The differences in device dimension do not raise different questions of S&E.
Sterilization	Sterilized by E-Beam radiation	Sterilized by ethylene oxide (ETO)	**Different.** The differences in device

			sterilization methods do not raise different questions of S&E.
Shelf-life	3 months	3 years	**Different.** The differences in shelf-life duration do not raise different questions of S&E
Mouse Embryo Assay (MEA)	One-cell MEA: ≥80% embryos developed to expanded blastocyst at 96h	One-cell MEA: ≥80% embryos developed to expanded blastocyst at 96h	Same
Bacterial Endotoxin Assay (BEA)	<20 EU/device	<20 EU/device	Same

The subject and predicate device have differences in their indications for use statements; however, their intended uses are the same (i.e., transfer of embryos to the uterine cavity). There are different technological characteristics, including differences in device components, materials, dimension, sterilization method, and shelf-life. The different technological characteristics do not raise different questions of safety and effectiveness.

6. Summary of Non-Clinical Performance Testing

The following studies have been performed to support substantial equivalence to the predicate device

Sterilization validation performed according to ISO 11137-1:2006/(R)2015 and ISO 11137-2:2013.

Packaging integrity testing according to ISO 11607-1:2019 and ISO 11607-2:2019

- Visual inspection per ASTM F1886/F1886M-16
- Dye penetration per ASTM F1929-15
- Seal strength per ASTM F88/F88M-23

Transportation simulation testing per ASTM 4169-22 and package integrity testing

Biocompatibility evaluation conducted in accordance with the 2023 FDA guidance document *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices –Part 1: Evaluation and testing within a risk management process."* Testing included the following assessments:

- Cytotoxicity per ISO 10993-5
- Sensitization per ISO 10993-10
- Irritation per ISO 10993-23

Testing showed the device material to be non-cytotoxic, non-sensitizing, and non-irritating.

Endotoxin testing (BEA) performed according to USP <85> and USP <161> with acceptance criteria < 20 EU/device.

Mouse embryo assay (MEA) performed per the 2021 FDA guidance document *Mouse Embryo Assay for Assisted Reproduction Technology Devices* with specification: One-Cell MEA: ≥80% embryos developed to expanded blastocysts within 96 hours.

Bench performance assessed before and after accelerated aging to the equivalent of three months of real-time aging in accordance with ASTM F1980-21:

- Visual inspection of device, packaging and labels
- Dimensional verification
- Compatibility testing with catheter, guide, and stylet
- Useable length verification of assembled guide and catheter
- Echogenic marking verification by ultrasound
- Verification of Luer lock connection per ISO 80369-7:2021
- Aspiration, flush, leak and flowrate tests of catheter per EN 1618
- Distance marking location and durability
- Curvature verification of Pre-curved guide
- Dislodgement force of positioning stopper
- Tensile strength testing of catheter
- Echogenic marking visibility test of catheter
- Tip drop angle of simulated loaded catheter when held horizontally

All test articles met the predetermined acceptance criteria in the tests, except for “tip drop when held horizontally.” The device labeling includes a precaution “Due to the soft nature of the catheter, when loaded, the catheter may bend. Ensure the tip of the catheter is properly aligned with the guide before inserting it into the guide during the embryo transfer procedure” to mitigate embryo loss risks.

7. Conclusion

The results of the performance testing described above demonstrate that the EmbryoCath Embryo Transfer Catheters (REFs 17500, 17501, 17502) and EmbryoCath Stylets (REFs 17510, 17511) are as safe and effective as the predicate device and supports a determination of substantial equivalence.