April 10, 2025

DonneVie Medical Technology (Shanghai) Co. Ltd.
Lily Liu
RA Manager
Suite 201, Bld. 1, 138 Xinjun Ring
Minhang District
Shanghai, 201114
CHINA

Re: K242561
Trade/Device Name: Dewin Reproductive Media (Dewin Vitrification Kit, Dewin Thawing Kit)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: March 5, 2025
Received: March 11, 2025

Dear Lily Liu:

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,

Michael T. Bailey -S

For
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)*
K242561

Device Name
Dewin Reproductive Media (Dewin Vitrification Kit, Dewin Thawing Kit)

Indications for Use *(Describe)*

Dewin Vitrification Kit is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Dewin Thawing Kit is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

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
K242561

I. SUBMITTER

Applicant: DonneVie Medical Technology (Shanghai) Co. Ltd.

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Phone: 86 (21) 347-81568
Contact Person: Lily Liu, RA Manager
Email: liulj@dewinivf.com

Date Prepared: April 07, 2025

II. DEVICE

Trade Name: Dewin Reproductive Media (Dewin Vitrification Kit, Dewin Thawing Kit)
Common Name: Assisted Reproduction Media
Regulation Name: Reproductive Media and Supplements
Regulation Number: 884.6180
Product Code: MQL (Media, Reproductive)
Regulatory Class: II

III. PREDICATE DEVICE

Vitrification Kit and Thawing Kit (K171748) from Kitazato Corporation. The predicate device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

Dewin Vitrification Kit and Dewin Thawing Kit include a set of five media intended for use in the vitrification and thawing of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos as part of InVitro Fertilization (IVF) procedures.

The Vitrification Kit and Thawing Kit media are offered in 2mL and 5mL volumes. Dewin Vitrification Kit includes two media components, Equilibration Solution (ES) and Vitrification Solution (VS), containing the cryoprotectants ethylene glycol, trehalose (only in VS), and dimethyl sulfoxide. During the vitrification process, embryos are first exposed to ES and then to VS. Using this methodology, the permeating cryoprotectants can replace water in the oocyte or PN through blastocyst stage embryos prior to vitrification and storage in liquid nitrogen.

Dewin Thawing Kit is composed of three media used stepwise for thawing and removing cryoprotectants from vitrified oocytes and PN through blastocyst stage embryos. It is composed of Thawing Solution (TS), Dilution Solution (DS) and Washing Solution (WS).

The primary ingredients of the vitrification and thawing media are water, sodium chloride, potassium chloride, sodium dihydrogen phosphate dihydrate, magnesium sulphate heptahydrate, calcium chloride, sodium bicarbonate, gentamicin sulfate, glucose, sodium-s-lactate, sodium pyruvate, alanyl glutamine, taurine, EDTA, phenol red, HEPES, HSA, trehalose, ethylene glycol, DMSO, non-essential amino acids. Cryoprotectants in the media include ethylene glycol (7.5% in ES, 15% in VS), DMSO (7.5% in ES, 15% in VS), and trehalose in VS, TS and DS.

The five solutions in the Dewin Vitrification Kit and Dewin Thawing Kit are aseptically filtered (storage vials sterilized by dry heat and radiation) and provided in glass bottles capped with a polypropylene screw-top cap. They are single-use only and have a shelf-life of 7 months when stored at 2-8°C.

V. INDICATIONS for USE

Dewin Vitrification Kit is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

Dewin Thawing Kit is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.

VI. COMPARISON OF INTENDED USE AND TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

A comparison of the intended use and technological features of the subject and predicate devices are described in the table below:

Comparison Item	K242561 Subject Device	K171748 Predicate Device	Comparison
Indication for Use	Dewin Vitrification Kit is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage	The Vitrification Kit is indicated for use in the preparation, vitrification, and storage of oocytes (MII), pronuclear (PN) zygotes through day 3	**Same Intended Use:** There are differences in the wording of the indications for use statements for the subject and predicate device;

Comparison Item	K242561 Subject Device	K171748 Predicate Device	Comparison
	embryos and blastocyst stage embryos. Dewin Thawing Kit is intended for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.	cleavage stage embryos, and blastocyst stage embryos. The Thawing Kit is indicated for use in the preparation and thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.	however, the intended uses of the subject and predicate device media are the same (i.e., vitrification and warming of oocytes and embryos).
Conditions for Use	Prescription Use Only	Prescription Use Only	**Same**
Kit components	Dewin Vitrification Kit includes two media components, Equilibration Solution (ES) and Vitrification Solution (VS). Dewin Thawing Kit is composed of three media, Thawing Solution (TS), Dilution Solution (DS) and Washing Solution (WS).	The Vitrification Kit includes three media components, Basic Solution (BS), Equilibration Solution (ES) and Vitrification Solution (VS). The Vitrification Kit comes prepackaged with 4 Cryotop devices (Cryotop CL, Cryotop SC, or Cryotop US), and 2 Repro Plates. The Thawing Kit is composed of TS (Thawing Solution), DS (Dilution Solution) and WS (Wash Solution). The Thawing Kit comes pre-packaged with one Repro	**Different:** There are differences in the number of media solutions between the subject and predicate devices. In addition, the predicate device includes additional components (vitrification storage devices and plates) that are not provided in the subject device kit. These differences do not raise different questions of safety and effectiveness (S&E).

Comparison Item	K242561 Subject Device	K171748 Predicate Device	Comparison
		Plate, and two 35 mm dishes.	
Freeze Kit Formulation	Water, sodium chloride, potassium chloride, sodium dihydrogen phosphate dihydrate, magnesium sulphate heptahydrate, calcium chloride, sodium bicarbonate, gentamicin sulfate, glucose, sodium-s-lactate, sodium pyruvate, alanyl glutamine, taurine, EDTA, phenol red, HEPES, HSA, trehalose, ethylene glycol, DMSO, non-essential amino acids.	Medium 199, Ethylene Glycol, DMSO, Trehalose, Hydroxypropyl Cellulose (HPC), Gentamicin	**Different:** The formulations of the subject and predicate devices are not the same. These differences in device formulations do not raise different questions of S&E.
Thaw Kit Formulation	Water, sodium chloride, potassium chloride, sodium dihydrogen phosphate dihydrate, magnesium sulphate heptahydrate, calcium chloride, sodium bicarbonate, gentamicin sulfate, glucose, sodium-s-lactate, sodium pyruvate, alanyl glutamine, taurine, EDTA, phenol red, HEPES, HSA, trehalose, non-essential amino acids.	Medium 199; Sucrose, Hydroxylpropyl Cellulose, Gentamicin, Trehalose	**Different:** The formulations of the subject and predicate devices are not the same. These differences in device formulations do not raise different questions of S&E.
pH	7.20-7.60	7.2-7.6	**Same**

Comparison Item	K242561 Subject Device	K171748 Predicate Device	Comparison
Osmolality (mOsmol/kg)	ES: 2300-3000mOsm/Kg VS: 4900-6600mOsm/Kg TS: 1255-1535mOsm/Kg DS: 745-911mOsm/Kg WS: 260-295 mOsm/Kg	ES: 2,300 – 2,800 VS: 4,900 – 6,000 TS: 1,600 – 2,000 DS: 830 - 1020 WS: 240 - 300	**Different:** The subject device and predicate devices have differences in osmolality specifications. These differences in osmolality specifications do not raise different questions of S&E.
Bacterial Endotoxin	< 0.25 EU/mL	< 0.25 EU/mL	**Same**
Mouse Embryo Assay	1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.	1-Cell MEA: ≥ 80% expanded blastocyst after 96 hours	**Same**
Sterilization Method	Aseptic Filtration Vials are sterilized via dry heat and radiation	Aseptic Filtration Vials are sterilized via radiation	**Different:** The differences in sterilization methods identified do not raise different questions of S&E.
Shelf-Life	7 months	12 months	Different

As shown in the table above, there are differences in the indications for use statements and technological characteristics of the subject and predicate devices. However, as stated in the table, the differences in indications for use do not represent a new intended use and the differences in technological characteristics do not raise different questions of safety and effectiveness.

VII. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING

The following studies have been conducted in support of the substantial equivalence to the predicate device.

- Aseptic filtration and aseptic filling validation, per ISO 13408-1:2008 & A1:2013 and ISO 13408-2:2018.

- For filter challenge test per ISO 13408-2, the solutions used for testing did not contain antimicrobials (gentamicin was excluded from subject media formulation) and were representative of worst-case production conditions.

- Vial glass bottles were sterilized by dry heat, per ISO 20857:2010/(R)2015 (Revision of ANSI/AAMI/ST63:2002) Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices. Vial caps were sterilized by radiation, per ISO 11137-1:2006 (including: Amendment 1 (2013) and Amendment 2 (2018)) Sterilization of health care products — Radiation — Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11137-2:2013 - Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose [Including Amendment 1 (2022)].
- Shelf-life testing was conducted to support a 7-month shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after real time aging:
  - Appearance: Clear, particulate free
  - pH per USP <791>: 7.20 - 7.60 (all solutions)
  - Osmolality per USP <785>: ES: 2300-3000 mOsm/Kg, VS: 4900-6600 mOsm/Kg, TS: 1255-1535 mOsm/Kg, DS: 745-911 mOsm/Kg, WS: 260-295 mOsm/Kg
  - Sterility per USP <71>: No microbial growth
  - Bacterial endotoxin per USP <85>: < 0.25 EU/mL
  - MEA per the 2021 FDA guidance *Mouse Embryo Assay for Assisted Reproduction Technology Devices*: 1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.
- Transportation testing per ASTM D4169-22 and cap/seal leak testing using a method equivalent to USP <1207.2> on transportation-conditioned devices.

VIII. CONCLUSION

The results of the performance testing described above demonstrate that Dewin Reproductive Media (Dewin Vitrification Kit, Dewin Thawing Kit) is as safe and effective as the predicate device and supports a determination of substantial equivalence.