August 26, 2025

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

Re: K251637
Trade/Device Name: Dewin Reproductive Media (Dewin Gamete Buffer [with HSA and without HSA]; Dewin Follicle Flushing Solution; Dewin One Step medium [with HSA and without HSA])
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media And Supplements
Regulatory Class: Class II
Product Code: MQL
Dated: May 29, 2025
Received: May 29, 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,

Monica D. Garcia -S

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)*
K251637

Device Name
Dewin Reproductive Media (Dewin Gamete Buffer [with HSA and without HSA]; Dewin Follicle Flushing Solution; Dewin One Step medium [with HSA and without HSA])

Indications for Use *(Describe)*

Dewin Gamete Buffer is intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracytoplasmic sperm injection (ICSI).

Dewin Follicle Flushing Solution is intended for use during ovarian follicle flushing and oocyte collection procedures for use in in vitro fertilization procedures.

Dewin One Step Medium is intended for use for culture of embryos from fertilization to the blastocyst stage. This device can be used for transfer of embryos to the uterus.

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**
**K251637**

## I. SUBMITTER


| | |
|---|---|
| Applicant: | DonneVie Medical Technology (Shanghai) Co. Ltd. |
| Address: | Suite 201, Bld. 1, 138 Xinjun Ring Minhang District, Shanghai, 201114,China |
| Phone: | 86 (21) 347-81568 /86 18221012749 |
| Contact Person: | Lily Liu, RA Manager |
| Email: | liulj@dewinivf.com |
| Date Prepared: | July 31, 2025 |


## II. DEVICE

| | |
|---|---|
| Trade Name: | Dewin Reproductive Media (Dewin Gamete Buffer [with HSA and without HSA]; Dewin Follicle Flushing Solution; Dewin One Step medium [with HSA and without HSA]) |
| 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

VitaVitro Fertilization Medium, VitaVitro Gamete Buffer Medium, VitaVitro Flushing Buffer Medium (K200408) from Shenzhen VitaVitro Biotech Co.,Ltd. The predicate device has not been subject to a design-related recall.

## IV. DEVICE DESCRIPTION

The DonneVie Dewin Reproductive Media are solutions used in assisted reproductive procedures. The family of Reproductive Media include the following 3 types and their variants:

- Dewin Gamete Buffer [with and without Human Serum Albumin (HSA)] ;
- Dewin Follicle Flushing Solution ;
- Dewin One Step Medium [with and without HSA].

All variants contain gentamicin, an antibiotic agent that suppresses bacterial growth. The Gamete Buffer and Follicle Flushing media are offered in 100mL volume, while the One Step Medium is offered in volumes of 25mL and 50mL. The three Dewin Reproductive Media are used together during an assisted reproductive procedure. The Follicle Flushing Solution is used to first flush/wash the Cumulus-Oocyte Complex after it's removed from the ovary; it is then transferred to the Gamete Buffer for cleaning. After the prepared oocyte has been fertilized, it is transferred to the One Step Medium to culture the embryo from fertilization to blastocyst stage.

The primary glass bottle containers are washed, then sterilized and depyrogenated via dry heat. The bottle caps are supplied sterile by electron beam irradiation. The media are sterile filtered through a 0.2μm filter in an aseptic isolator at DonneVie Medical Technology Co., Ltd.

## V. INDICATIONS for USE

Dewin Gamete Buffer is intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracytoplasmic sperm injection (ICSI).

Dewin Follicle Flushing Solution is intended for use during ovarian follicle flushing and oocyte collection procedures for use in in vitro fertilization procedures.

Dewin One Step Medium is intended for use for culture of embryos from fertilization to the blastocyst stage. This device can be used for transfer of embryos to the uterus.

## 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 tables below:

**Table 1 – Dewin Gamete Buffer & Follicle Flushing Solution Comparison to VitaVitro Gamete Buffer Medium & VitaVitro Flushing Buffer Medium**

| | Subject device - Dewin Reproductive Media (Dewin Gamete Buffer [with HSA and without HSA]; Dewin Follicle Flushing Solution; Dewin One Step | Predicate device - VitaVitro® Fertilization Medium, VitaVitro® Gamete Buffer Medium, VitaVitro® Flushing Buffer Medium / K200408 | Comparison |
|---|---|---|---|

| | | | |
|---|---|---|---|
| | medium [with HSA and without HSA]) | | |
| Indications for Use | Dewin Gamete Buffer is intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracytoplasmic sperm injection (ICSI).<br><br>Dewin Follicle Flushing Solution is intended for use during ovarian follicle flushing and oocyte collection procedures for use in in vitro fertilization procedures.<br><br>Dewin One Step Medium is intended for use for culture of embryos from fertilization to the blastocyst stage. This device can be used for transfer of embryos to the uterus. | VitaVitro® Gamete Buffer Medium is intended for human gamete and embryo short-term handling procedures outside the incubator, including washing and intracytoplasmic sperm injection (ICSI).<br><br>VitaVitro® Flushing Buffer Medium is intended for use during ovarian follicle flushing and oocyte collection procedures for use in in vitro fertilization procedures.<br><br>VitaVitro® Fertilization Medium is intended for preparation and handling of human gametes and for in vitro fertilization. | The Indications for use statements are same for Gamete Buffer and Follicle Flushing Solution. The difference in language for One Step Medium and Fertilization Medium do not raise different questions of S&E. |
| Primary Ingredients | Inorganic salts, energy sources, amino acids, antibiotic, HSA, antioxidant, buffer, EDTA, phenol red. | Inorganic salts, energy sources, amino acids, antibiotic, HSA, antioxidant, buffer, EDTA, phenol red. | **Different:** The formulations of the subject and predicate devices are not the same. These differences do not raise different questions of S&E. |
| pH | 7.2 – 7.5 | 7.2 - 7.6 | **Different:** The subject device and predicate devices have differences in pH specifications. These differences do not raise different questions of S&E. |
| Osmolality | 260-295mOsm/Kg | 260 - 290mOsm/Kg | **Different:** The subject device and predicate devices have differences in |

| | | | |
|---|---|---|---|
| | | | osmolality specifications. These differences do not raise different questions of S&E. |
| Endotoxin | <0.25EU/mL | <0.25EU/mL | **Same** |
| MEA | One-cell MEA: ≥80% developed to expanded blastocyst at 96 hours after a 30 minute exposure to Dewin Gamete Buffer.<br><br>One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 30 minute exposure to Dewin Follicle Flushing Solution.<br><br>One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 120 hours for Dewin One Step medium. | 1-cell MEA: ≥80% expanded blastocyst at 96 hours after a 2-hour exposure to media (Gamete Buffer Medium and Flushing Buffer Medium).<br><br>1-cell MEA: ≥80% expanded blastocyst at 96 hours after a 24-hour exposure to media (Fertilization media). | **Different:** The subject device and predicate devices have differences in MEA specifications. These differences do not raise different questions of S&E. |
| Sterilization method | Aseptic filtration. | Aseptic filtration. | **Same** |
| Storage conditions | 2 - 8°C | 2 - 8°C | **Same** |
| Shelf-life | Dewin Gamete Buffer – 7 months<br>Dewin Follicle Flushing Solution – 12 months<br>Dewin One Step Medium – 4 months. | 6 months. | **Different:** The subject device and predicate devices have differences in shelf-life. These differences do not raise different questions of S&E. |

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 raise different questions of safety and effectiveness 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 devices:

- 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.
- Glass bottles were sterilized by dry heat, per 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. Bottle 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 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>: 7.2 -7.5
    - Osmolarity per USP <785>: 260–295 mOsm/kg
    - Endotoxin per USP <85>: < 0.25 EU/mL
    - Sterility per USP <71>: No microbial growth
    - MEA per the 2021 FDA Guidance *Mouse Embryo Assay for Assisted Reproduction Technology Devices*:
        - One Step Medium: One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 120 hours for Dewin One Step medium
        - Gamete Buffer: “One-cell MEA: ≥80% developed to expanded blastocyst at 96 hours after a 30 minute exposure to Dewin Gamete Buffer

- Follicle Flushing Solution: One-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours after a 30 minute exposure to Dewin Follicle Flushing Solution

- Transportation testing per ASTM D4169-22 and cap/seal leak testing using a method equivalent to USP <1207.2> on transportation-conditioned devices.

- Biocompatibility testing was conducted on the patient contacting subject media Dewin Follicle Flushing Solution and Dewin One Step Medium 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,* as follows:

  - Cytotoxicity (ISO 10993-5:2009)
  - Guinea Pig Maximization Sensitization Test (ISO 10993-10:2021)
  - Intracutaneous Reactivity (ISO 10993-23:2021)

  The results of the testing conducted support the biocompatibility of the patient contacting subject devices.

## VIII. CONCLUSION

The results of the performance testing described above demonstrate that Dewin Reproductive Media (Dewin Gamete Buffer, Dewin Follicle Flushing Solution and Dewin One Step Medium) are as safe and effective as the predicate device and supports a determination of substantial equivalence.