August 4, 2023

DonneVie Medical Technology (Shanghai) Co. Ltd.
℅ Stuart R. Goldman
Senior Regulatory Consultant, RA/QA
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, TX 78746

Re: K231370
Trade/Device Name: Dewin Blastocyst Medium (with HSA and without HSA)
Regulation Number: 21 CFR§ 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL
Dated: May 10, 2023
Received: May 12, 2023

Dear Stuart R. Goldman:

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. 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 located 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.

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

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 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)*
K231370

Device Name
Dewin Blastocyst Medium (with HSA and without HSA)

Indications for Use *(Describe)*
Dewin Blastocyst Medium (with HSA and without HSA) is intended for culture from the 8-cell stage to the blastocyst stage of embryo development. Dewin Blastocyst Medium (with HSA and without HSA) is also intended for use in transfer of blastocyst stage embryos into the uterine cavity.

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

Dewin Blastocyst Medium (with HSA and without HSA)

K231370

1. Submission Sponsor

DonneVie Medical Technology (Shanghai) Co. Ltd.
Suite 201, Bld. 1, 138 Xinjun Ring
Minhang District, Shanghai, 201114, China
Contact: Hannah Hang Yin
Phone: +86 21 34781568
Title: CEO

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
Building 1, Suite 300
Austin, TX 78746
Office Phone: (512) 327-9997
Email: LST.AUS.ProjectManagement@ul.com
Contact: Stuart R. Goldman
Title: Senior Regulatory Consultant, RA/QA

3. Date Prepared

July 31, 2023

4. Device Identification

Trade/Proprietary Name:	Dewin Blastocyst Medium (with HSA and without HSA)
Common/Usual Name:	Reproductive Media
Regulation Name:	Reproductive media and supplements
Regulation Number:	884.6180
Product Code:	MQL (Media, Reproductive)
Class:	Class II

5. Legally Marketed Predicate Device

Device name:	Sydney IVF Blastocyst Medium
510(k) number:	K153290
Manufacturer:	William A. Cook Australia Pty, Ltd.

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

6. Device Description

Dewin Blastocyst Medium (with HSA and without HSA) is intended for embryo culture from the cleavage to blastocyst stage of development and can also be used for transfer of blastocyst stage embryos to the uterine cavity.

Dewin Blastocyst Medium is comprised of salts, buffering agents, energy substrates, antioxidant, vitamins, nutrient supplements, amino acids, and gentamicin. Dewin Blastocyst Medium is offered with and without Human Serum Albumin (HSA).

Dewin Blastocyst Medium (with HSA and without HSA) is aseptically filtered and filled into glass bottles with polypropylene caps. The device is provided in 25 mL and 50 mL volumes. Dewin Blastocyst Medium (with HSA and without HSA) has a four-month shelf-life when stored as recommended and is for single-use only.

7. Indication for Use

Dewin Blastocyst Medium (with HSA and without HSA) is intended for culture from the 8-cell stage to the blastocyst stage of embryo development. Dewin Blastocyst Medium (with HSA and without HSA) is also intended for use in the transfer of blastocyst stage embryos into the uterine cavity.

8. Comparison of intended use and technological characteristics of the subject and predicate devices

A comparison of the intended use and technological characteristics of the subject device and the predicate device is shown in the table below:

Table 1. Comparison of Characteristics

	Dewin Blastocyst Medium (with HSA and without HSA)	**Cook Sydney Blastocyst Medium (Predicate – K153290)**	**Discussion**
Manufacturer	DonneVie Medical Technology (Shanghai) Co. Ltd.	William A. Cook Australia Pty, Ltd.	
Product Code	MQL	MQL	
Regulation Number	884.6180	884.6180	
Class	Class II	Class II	
Indications for Use	Dewin Blastocyst Medium (with HSA and without HSA) is intended for culture from the 8-cell stage to the blastocyst stage of embryo development. Dewin Blastocyst Medium (with HSA and without HSA) is also intended for use in the transfer of blastocyst stage embryos into the uterine cavity.	Sydney IVF Blastocyst Medium is intended for use during in vitro fertilization procedures for extended culture and transfer of embryos.	There are differences in the indications for use statements for the subject and predicate devices; however, the intended uses of the subject and predicate devices are the same (i.e., culture of embryos from the cleavage to blastocyst stage of development and for blastocyst transfer). Therefore, they have the same intended use.
Conditions of Use	Rx Only	Rx Only	Same
Device Materials	Salts, buffer, energy substrates, antioxidant, vitamins, nutrient supplements, amino acids, and gentamicin. It is offered with and without HSA.	Salts, energy substrates, buffer, antioxidant, nutrient supplements, amino	**Different:** The formulations of the subject and predicate devices are not the same. Differences in device formulations do not raise

		acids, gentamicin, and HSA.	different questions of safety and effectiveness (S&E).
Volumes	25, 50 mL	20, 50 mL	Similar
Aseptically Filtered	Yes	Yes	Same
Single-Use	Yes	Yes	Same
Storage Condition	2 – 8°C	2 – 8°C	Same
Shelf Life	4 months	20 weeks	**Different:** The subject device has a shorter shelf-life than the predicate device. Differences in shelf-life do not raise different questions of S&E.
pH	7.2–7.5	7.5 –7.8	**Different:** The subject device has a lower pH range than the predicate device. This difference in pH range does not raise different questions of S&E.
Osmolality	260-295 mOsm/kg	280-290 mOsm/kg	**Different:** The subject device has a wider osmolality range than the predicate device. This difference in osmolality does not raise different questions of S&E.
Endotoxin	< 0.25 EU/mL	< 0.4 EU/mL	**Different:** The subject device has a lower endotoxin specification than the predicate device. This difference does not raise different questions of S&E.
MEA	One-cell system: ≥ 80% embryos developed to expanded blastocyst at 96 hours	2-cell MEA: ≥ 80% expanded blastocyst at 72 hours	**Different:** There are differences in the type of MEA testing conducted. This difference in MEA method does not raise different questions of S&E.

As shown in the table above, there are differences in the indications for use statements and technological features 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 features do not raise different questions of safety and effectiveness.

9. Non-Clinical Performance Data

To demonstrate safety and effectiveness of Dewin Blastocyst Medium (with HSA and without HSA) and to show substantial equivalence to the predicate device, DonneVie Medical Technology completed the following non-clinical tests. Results confirm that the design inputs and performance specifications for the device are met.

- Biocompatibility testing was conducted in support of the Dewin Blastocysts Medium that will have direct contact with the patient during embryo transfer procedures. Testing was conducted in accordance with the 2020 FDA guidance *Use of International Standard ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and testing within a risk management process*. Testing included:
  - Cytotoxicity testing per ISO 10993-5:2009

  - Sensitization testing per ISO 10993-10:2010
  - Intracutaneous Reactivity per ISO 10993-10:2010

  The testing demonstrated the Dewin Blastocyst Medium formulation to be non-cytotoxic, non-sensitizing, and non-irritating.
- Sterile filtration and aseptic fill validation, per ISO 13408-1:2008 and ISO 13408-2:2018.
- Shelf-life testing was conducted to support the 4-month shelf-life through demonstration that the product specifications (shown below) were met at time 0 and after real-time aging in accordance with ASTM F1980-16:
  - Appearance: Clear, particle-free
  - pH, per USP <791>: 7.2–7.5
  - Osmolality, per USP<785>: 260–295 mOsm/kg
  - Endotoxin, per USP <85>: < 0.25 EU/mL
  - MEA testing, in accordance with the 2021 FDA guidance *Mouse Embryo Assay for Assisted Reproduction Technology Devices*:
    - Dewin Blastocyst Medium: One-cell system: ≥80% embryos developed to expanded blastocyst at 96 hours
  - Sterility, per USP <71>: No microbial growth
- Transportation testing per ASTM D4169-16

10. Statement of Substantial Equivalence

The results of the performance testing described above demonstrate that the subject medium is as safe and effective as the predicate device and supports a determination of substantial equivalence.