June 16, 2022

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: K212426
Trade/Device Name: Dewin Reproductive Media (Dewin Fertilization Medium [with HSA and without HSA] and Dewin Cleavage 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, 2022
Received: May 17, 2022

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212426

Device Name
Dewin Reproductive Media (Dewin Fertilization Medium [with HSA and without HSA] and Dewin Cleavage Medium [with HSA and without HSA])

Indications for Use *(Describe)*

Dewin Reproductive Media consists of Dewin Fertilization Medium (with HSA and without HSA) and Dewin Cleavage Medium (with HSA and without HSA). The indications for use for the Dewin Fertilization Medium and Dewin Cleavage Medium are as follows:

Dewin Fertilization Medium is intended for use during in vitro fertilization (IVF) procedures and culture to the two pronuclei (zygote) stage of development. Dewin Fertilization Medium is also intended for washing and handling sperm and collected oocytes after aspiration prior to IVF procedures. Dewin Fertilization Medium is not intended for use in intrauterine insemination procedures.

Dewin Cleavage Medium is intended for culture of embryos from the two pronuclei (zygote) stage to the 8-cell stage of embryo development. Dewin Cleavage Medium is also intended for use in the transfer of cleavage 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Dewin Reproductive Media (Dewin Fertilization Medium [with HSA and without HSA], Dewin Cleavage Medium [with HSA and without HSA])
K212426

1. Sponsor Information

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. Correspondent Information

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

June 15, 2022

4. Device Identification

Trade/Proprietary Name:	Dewin Reproductive Media (Dewin Fertilization Medium [with HSA and without HSA], and Dewin Cleavage 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(s)

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

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

6. Device Description

Dewin Reproductive Media includes two products (Dewin Fertilization Medium and Dewin Cleavage Medium). Dewin Fertilization Medium is intended for use in washing and handling sperm and oocytes for use in in IVF procedures. Dewin Cleavage Medium, is intended for use in culturing embryos from the zygote stage to the 8-cell stage of development and can also be used for embryo transfer procedures.

Dewin Reproductive Media are comprised of salts, energy substrates, anti-oxidant, nutrient supplements, amino acids, EDTA, gentamicin, and phenol red. Dewin Reproductive Media are offered with and without Human Serum Albumin (HSA).

The Dewin Reproductive Media are aseptically filtered and filled into glass bottles with polypropylene caps. The devices are provided in 25 mL and 50 mL volumes. Dewin Reproductive Media have a four-month shelf-life when stored as recommended and are for single-use only.

7. Indications for Use

Dewin Reproductive Media consists of Dewin Fertilization Medium (with HSA and without HSA) and Dewin Cleavage Medium (with HSA and without HSA). The indications for use for the Dewin Fertilization Medium and Dewin Cleavage Medium are as follows:

Dewin Fertilization Medium is intended for use during vitro fertilization (IVF) procedures and culture to the two pronuclei (zygote) stage of development. Dewin Fertilization Medium is also intended for washing and handling sperm and collected oocytes after aspiration prior to IVF procedures. Dewin Fertilization Medium is not intended for use in intrauterine insemination procedures.

Dewin Cleavage Medium is intended for culture of embryos from the two pronuclei (zygote) stage to the 8-cell stage of embryo development. Dewin Cleavage Medium is also intended for use in the transfer of cleavage 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:

	Dewin Reproductive Media – K212426 (Subject Device)	**Cook Sydney IVF Media – K153290 (Predicate Device)**	**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 Reproductive Media consists of Dewin Fertilization Medium (with HSA and without HSA) and Dewin Cleavage Medium (with HSA and without HSA). The indications for use for the Dewin Fertilization Medium and Dewin Cleavage Medium are as follows: Dewin Fertilization Medium is intended for use during vitro fertilization (IVF) procedures and culture to the two pronuclei (zygote) stage of development. Dewin Fertilization Medium is also intended for washing and handling sperm and collected oocytes after aspiration prior to IVF procedures. Dewin Fertilization Medium is not intended for use in intrauterine insemination procedures. Dewin Cleavage Medium is intended for culture of embryos from the two pronuclei (zygote) stage to the 8-cell stage of embryo development. Dewin Cleavage Medium is also intended for use in the transfer of cleavage stage embryos into the uterine cavity.	Sydney IVF Fertilization Medium is intended for use during in vitro procedures for insemination and incubation of oocytes. Sydney IVF Cleavage Medium is intended for use during in vitro fertilization procedures for culture and transfer of cleavage stage 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. Therefore, they have the same intended use.
Conditions of Use	Rx Only	Rx Only	Same
Device Materials	Salts, energy substrates, anti-oxidant, nutrient supplements, amino acids, EDTA, gentamicin, and phenol red. It is offered with and without HSA.	Salts, energy substrates, buffer, anti-oxidant, nutrient supplements, amino acids, antibiotic, protein	**Different:** The formulations of the subject and predicate devices include the same types of chemical constituents; however, the formulations are not the same. Differences in device formulations do not raise different questions of safety and effectiveness (S&E).
Volume	25, 50 mL	20, 50, 100 mL	**Different:** The subject and predicate devices are provided in different volumes. Differences in volumes do not

			raise different questions of S&E.
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	285-295 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.
Sterility	No microbial growth	No microbial growth	Same
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 after 24-hour exposure to Dewin Fertilization Medium One-cell system: ≥80% embryos developed to expanded blastocyst at 96	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 both methods are acceptable to

	hours after 48-hour exposure to Dewin Cleavage Medium		support an assisted reproduction media device.

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 Testing

To demonstrate safety and effectiveness of Dewin Reproductive Media 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 Cleavage 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 Cleavage Medium formulations 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 for both products through demonstration that the product specifications (shown below) were met at time 0 and after accelerated 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 Fertilization Medium: One-cell system: ≥80% embryos developed to expanded blastocyst at 96 hours after 24-hour exposure to Dewin Fertilization Medium
    - Dewin Cleavage Medium: One-cell system: ≥80% embryos developed to expanded blastocyst at 96 hours after 48-hour exposure to Dewin Cleavage Medium
  - 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 media products are as safe and effective as the predicate devices and support a determination of substantial equivalence.