April 10, 2025

Jiangsu Ruifuda Medical Device Co., Ltd
% Olivia Meng
RA Director
Guangzhou Osmunda Medical Device Technical Service Co., Ltd.
14F, Bldg C, Ancillary Project of Phase IV Standard
Industrial Park, Guangzhou International Bio-Island
Guangdong, 510320
CHINA

Re: K242089
Trade/Device Name: Vitrification Freeze Kit (RFD-0101);
Vitrification Thaw Kit (RFD-0201, RFD-0202)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media And Supplements
Regulatory Class: II
Product Code: MQL
Dated: March 4, 2025
Received: March 7, 2025

Dear Olivia Meng:

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
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242089

Device Name
Vitrification Freeze Kit (RFD-0101); Vitrification Thaw Kit (RFD-0201, RFD-0202)

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

Vitrification Thaw 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
K242089

1. Contact Details

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Date Prepared	April 10, 2025

2. Device Name

Trade Name	Vitrification Freeze Kit (RFD-0101); Vitrification Thaw Kit (RFD-0201, RFD-0202)
Common Name	Assisted Reproduction Media
Classification Name	Reproductive media and supplements
Regulation	884.6180
Class	Class II
Product Code(s)	MQL (Media, Reproductive)

3. Predicate Device

510(k) #	K173731
Sponsor	Origio A/S
Trade Name	SAGE Vitrification Kit (ART-8025 and ART-8026) SAGE Vitrification Warming Kit (ART-8030 and ART-8031)
	The predicate device has not been subject to a design-related recall.

4. Device Description

The Vitrification Freeze Kit is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos during the in vitro assisted reproduction. The Vitrification Freeze Kit includes two solutions: Equilibration Solution (ES) and Vitrification Solution (VS). Both solutions contain ethylene glycol, dimethyl sulfoxide (DMSO), human serum albumin, and Quinn's Advantage® Medium with HEPES. The VS also contains additional sucrose to confer intracellular and extracellular cryoprotective effects. The solutions are available in three specifications: 2 mL, 4.5 mL, and 5 mL, all packaged in polypropylene (pp) vials. The kit includes one vial of each solution.

The Vitrification Thaw 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 during in vitro assisted reproduction. The Vitrification Thaw Kit includes 4 solutions: Thawing Solution 1 (TS1), Thawing Solution 2 (TS2), Thawing Solution 3 (TS3), and Thawing Solution 4 (TS4). All four solutions contain human serum albumin and Quinn's Advantage® Medium with HEPES. TS1 and TS2 also contain sucrose. The solutions are available in three specifications: 2 mL, 4.5 mL, and 5 mL, all packaged in polypropylene (pp) vials. Model RFD-0201 includes one vial of each solution in the kit, and Model RFD-0202 contains two vials of TS1 and one vial of TS2, TS3, and TS4 each in the kit.

5. Indications for Use

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

Vitrification Thaw 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.

6. Comparison of the Subject and Predicate Device Intended Use and Technological Characteristics

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

	K242089 **Vitrification Freeze Kit (RFD-0101); Vitrification Thaw Kit (RFD-0201, RFD-0202)**	**K173731** **SAGE Vitrification Kit (ART-8025 and ART-8026); SAGE Vitrification Warming Kit (ART-8030 and ART-8031)**	**Comparison**

Indications for Use	Vitrification Freeze Kit is intended for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. Vitrification Thaw 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.	SAGE 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. SAGE Vitrification Warming Kit is intended for use in the thawing of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.	Same
Conditions for Use	Prescription Use Only	Prescription Use Only	Same
Solutions	Vitrification Freeze Kit: Equilibration Solution; Vitrification Solution Vitrification Thaw Kit: Thawing Solution 1; Thawing Solution 2; Thawing Solution 3; Thawing Solution 4	SAGE Vitrification Kit: Equilibration Solution; Vitrification Solution SAGE Vitrification Warming Kit: 1.0 M Sucrose Warming Solution; 0.5 M Sucrose Warming Solution; MOPS Solution	**Different:** There are differences in the medium solutions for the subject and predicate devices; however, these differences do not raise different questions of S&E.
Formulation	Ethylene glycol; DMSO; Sucrose; Gentamicin; Human Serum Albumin; Quinn's Advantage® Medium with HEPES	Ethylene glycol; DMSO; Sucrose; Gentamicin; Human Serum Albumin; Modified Human Tubal Fluid (MOPS-Buffered); Amino Acids	**Different:** The formulation of the predicate device is not known; however, the differences in media product formulations do not raise different questions of S&E.
Sterilization	Aseptic filtration	Aseptic filtration	Same
Sterility	No growth	No growth	Same

pH	7.30-7.70	7.20-7.40	**Different:** The subject device has a higher pH range than the predicate device. This difference in pH range does not raise different questions of S&E.
Endotoxin (EU/ml)	<0.5	<0.5	Same
Osmolality (mOsm/kg)	ES: 700±70 (1:3 dilution) VS: 1,000±80 (1:5 dilution) TS1: 1500-1900 TS2: 840-920 TS3: 240-300 TS4: 240-300	ES: 2331-2,849 VS: 5,603-6,849 1.0 M WS: 1,255-1,535 0.5 M WS: 745-911 MS: 257-273	**Different:** The subject device has a lower osmolality level than the predicate device. This difference in osmolality specifications does not raise different questions of S&E.
MEA	One-cell system: ≥ 80% embryos developed to expanded blastocyst at 96 hours	One-cell system: ≥ 80% blastocyst at 96 hours	Same
Storage	2-8°C	2-8°C	Same
Shelf Life	7 weeks	52 weeks	**Different:** The subject device has a shorter shelf life than the predicate device. Difference 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, the subject and predicate devices have the same intended use and the differences in technological features do not raise different questions of safety and effectiveness.

7. Summary of Non-Clinical Performance Testing

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

- Aseptic filtration and aseptic filling validation, per ISO 13408-1:2008 – Aseptic Processing of Health Care Products – Part 1 General Requirements (including Amendment 1 (2013)) and ISO 13408- 2:2018 – Aseptic Processing of Health Care Products – Part 2 Sterilizing Filtration.
- Shelf-life testing was conducted to support the 7-week shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after real-time aging. Testing conducted is shown below:

  Appearance: pH (USP <791>): 7.30-7.70
  Osmolality (USP <785>) (mOsm/kg):
  Equilibration Solution (ES): 700±70 (ES:purified water=1:3)
  Vitrification Solution (VS): 1000±80 (VS:purified water=1:5)
  Thawing Solution 1 (TS1): 1500-1900
  Thawing Solution 2(TS2): 840-920
  Thawing Solution 3 (TS3): 240-300
  Thawing Solution 4 (TS4): 240-300
  Endotoxin testing (USP <85>): <0.5 EU/mL
  Mouse Embryo Assay (MEA): One-Cell System: ≥80% embryos developed to expanded blastocyst at 96 hours
  Sterility testing (USP <71>): No microbial growth

- Transportation testing per ASTM D4169-22 and USP <1207.2>.

8. Conclusions

The results of the performance testing described above demonstrated that the Vitrification Freeze Kit and Vitrification Thaw Kit are as safe and effective as the predicate devices and support a determination of substantial equivalence.