August 28, 2026

Cell Store (Beijing) Biotechnology Co., Ltd.
Kang Zhang
RA Director
Rm. 201 B2 Diamond Center, #66 Xixiaokou Rd.
Haidian District
Beijing, 100192
CHINA

Re: K254261
Trade/Device Name: Vitrification Freeze Kit and Thawing Kit
(CS-IVF-FK; CS-IVF-TK)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and supplements
Regulatory Class: II
Product Code: MQL
Dated: July 20, 2026
Received: July 21, 2026

Dear Kang Zhang:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254261

Device Name
Vitrification Freeze Kit and Thawing Kit (CS-IVF-FK; CS-IVF-TK)

Indications for Use *(Describe)*
The Vitrification Freeze Kit (Model. CS-IVF-FK) is indicated for use in the vitrification of oocytes (MII), day 3 cleavage stage embryos, and blastocyst stage embryos.

The Thawing Kit (Model. CS-IVF-TK) is indicated for use in the thawing of vitrified oocytes (MII), 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
K254261

1. Submitter Information

Applicant: CELL STORE (BEIJING) BIOTECHNOLOGY CO., LTD.
Address: Room 101, 5th Floor, Building 10, Yard 6, Dongsheng Science Park North Street, Haidian District, Beijing, China

2. Submission Correspondent

Contact: Kang Zhang
Role: RA Director
Company: CELL STORE (BEIJING) BIOTECHNOLOGY CO., LTD.
Address: Room 101, 5th Floor, Building 10, Yard 6, Dongsheng Science Park North Street, Haidian District, Beijing, China
Phone: +86 13811621417
Email: zhangkang@cellstorebio.com

3. Date prepared: August 27, 2026

4. Device Information

Device Name:	Vitrification Freeze Kit and Thawing Kit (CS-IVF-FK; CS-IVF-TK)
Common Name:	Assisted Reproduction Media
Regulation Number:	21 CFR 884.6180
Regulation Name:	Reproductive Media and Supplements
Product Code:	MQL (Media, Reproductive)
Regulatory Class:	Class II

5. Predicate Device Information

Device Name:	Vitrification Kit and Thawing Kit
510(k) Number:	K171748
Sponsor:	Kitazato Corporation.

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

6. Device Description

The Vitrification Freeze Kit and Thawing Kit (CS-IVF-FK; CS-IVF-TK) are composed of a set of six media to vitrify and warm MII oocytes, day 3 cleavage stage embryos, and blastocyst stage embryos.

The Vitrification Freeze Kit includes two media, equilibration solution and vitrification solution, containing the cryoprotectants ethylene glycol, sucrose. During the vitrification process, the oocytes and embryos are first exposed to the equilibration solution and then to vitrification solution. Using this methodology, the permeating cryoprotectants can replace water in the oocytes and embryos in the cleavage stage and blastocyst stage prior to vitrification and storage in the liquid nitrogen. The Vitrification Freeze Kit comes prepackaged

with one 4.5ml vial of equilibration solution (ES) and one 4.5ml vial of vitrification solution (FS).

The Thawing Kit is composed of four media used stepwise for thawing and removing cryoprotectants from vitrified oocytes, cleavage stage embryos, and blastocyst stage embryos. The Thawing Kit is composed of TS (Thawing Solution), DS1 (Dilution Solution 1), DS2 (Dilution Solution 2), and DS3 (Dilution Solution 3). The Thawing kit comes prepackaged one 4.5ml vial thawing solution, one 4.5ml vial dilution solution 1, one 4.5ml vial dilution solution 2, and one 4.5ml vial dilution solution 3.

The base medium for the vitrification freeze and thawing media includes water, salts, buffering agents, minerals, chelating agents, energy substrates, amino acids, polymeric substance, and gentamicin. Cryoprotectants in the media include ethylene glycol, and sucrose. The Six solutions in the Vitrification Freeze Kit and Thawing Kit are aseptically filtered (storage vials sterilized by radiation) and provided in polypropylene vials. They have a shelf-life of 6 months when stored at 2-8°C.

7. Indications for Use Statement

The Vitrification Freeze Kit (Model. CS-IVF-FK) is indicated for use in the vitrification of oocytes (MII), day 3 cleavage stage embryos, and blastocyst stage embryos.

The Thawing Kit (Model. CS-IVF-TK) is indicated for use in the thawing of vitrified oocytes (MII), day 3 cleavage stage embryos, and blastocyst stage embryos.

8. Comparison of Intended Use and Technological Characteristics with the Predicate Device

The table below includes a comparison of the intended use and technological characteristics of the subject and predicate devices.

	Vitrification Freeze Kit and Thawing Kit K254261 (Subject Device)	**Vitrification Kit and Thawing Kit K171748 (Predicate Device)**	**Comparison**
Regulation Number	21 CFR 884.6180	21 CFR 884.6180	Same
Product Code	MQL	MQL	Same
Classification	Class II	Class II	Same
Indications for Use	The Vitrification Freeze Kit (Model. CS-IVF-FK) is indicated for use in the vitrification of oocytes (MII), day 3 cleavage stage embryos, and blastocyst stage embryos. The Thawing Kit (Model. CS-IVF-TK) is indicated for use in the thawing of vitrified oocytes (MII), day 3 cleavage stage embryos, and blastocyst stage embryos.	The Vitrification Kit is indicated for use in the preparation, vitrification, and storage of oocytes (MII), pronuclear (PN) zygotes through day 3 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	**Different:** There are differences in the wording of the indications for use statements for the subject and predicate device; however, the intended uses of the subject and predicate device media are the same (i.e., vitrification and warming of oocytes and embryos).

		embryos, and blastocyst stage embryos.	
Conditions for Use	Prescription Use Only	Prescription Use Only	**Same**
Kit components	The Vitrification Freeze Kit includes Equilibration Solution (ES) and Vitrification Solution (FS). The Thawing Kit includes Thawing Solution (TS) and Dilution Solution 1 (DS1), Dilution Solution 2 (DS2), Dilution Solution 3 (DS3).	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 Plate, and two 35 mm dishes.	**Different:** The predicate device includes an additional basic solution component, equipment to conduct the procedure (plates), and a closed cryopreservation storage device that are different than the subject device. These differences do not raise different questions of safety and effectiveness (S&E).
Freeze Kit Formulation	Base medium (water, salts, buffering agents, minerals, chelating agents, energy substrates, amino acids, polymeric substance, gentamicin) with Poly(vinyl alcohol), Human albumin ,Cryoprotectants Ethylene Glycol and Sucrose	Medium 199, Ethylene Glycol, DMSO, Sucrose, Dextran Serum Supplement, Gentamicin	**Different:** The formulations of the subject and predicate devices are not the same. Differences in device formulations do not raise different questions of S&E.
Thaw Kit Formulation	Base medium (water, salts, buffering agents, minerals, chelating agents, energy substrates, amino acids, polymeric substance, gentamicin) with Poly(vinyl alcohol), Human albumin ,Cryoprotectant Sucrose	Medium 199; Sucrose, Dextran Serum Supplement, Gentamicin	**Different:** The formulations of the subject and predicate devices are not the same. Differences in device formulations do not raise different questions of S&E.
pH	7.2 – 7.6	7.2 – 7.6	Same
Osmolality (mOsm/kg)	Equilibration Solution:1500-1900 (1:1 dilution) Vitrification Solution: 2045-2445 (1:2 dilution)	Not available publicly	**Different:** The subject device and predicate devices have differences in osmolality specifications. These differences in osmolality

	Thawing Solution: 1546-1946 Dilution Solution 1: 860-960 Dilution Solution 2: 530-610 Dilution Solution 3: 275-300		specifications do not raise different questions of S&E.
Bacterial Endotoxin	<0.25 EU/mL	≤ 0.25 EU/mL	**Similar**
Mouse Embryo Assay (MEA)	1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.	1-Cell MEA: ≥ 80% embryos developed to expanded blastocyst at 96 hours.	Same
Sterilization method	Aseptic Filtration	Aseptic Filtration	Same
Storage	2 - 8°C	2 - 8°C	Same
Shelf-life	6 months	1 year	**Different:** Differences in shelf-life 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 including differences in vitrification and thaw kit formulation, specifications, and shelf life. However, as stated in the table above, 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.

9. 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 13408-1:2023 and ISO 13408-2:2018.
- Vial radiation sterilization, per ISO 11137-1:2025 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 6-month shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after accelerated aging in accordance with ASTM F1980-21:

  i. Appearance: Uniform color, clear and transparent, free of particles and precipitates

  ii. pH per USP <791>: 7.2 – 7.6 for all solutions

iii. Osmolality per USP <785>: Equilibration Solution:1500-1900 (1:1 dilution), Vitrification Solution: 2045-2445 （1:2 dilution), Thawing Solution: 1546-1946, Dilution Solution 1: 860-960, Dilution Solution 2: 530-610, Dilution Solution 3: 275-300

iv. Sterility per USP <71>: No microbial growth

v. Bacterial endotoxin per USP <85>: < 0.25 EU/mL

vi. 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.

10. Conclusion

The results of the performance testing described above demonstrate that the subject devices are as safe and effective as the predicate device and support a determination of substantial equivalence.