July 1, 2024

Shandong Wego Ruisheng Medical Device Co., Ltd
% Eva Li
Consultant
Shanghai SUNGO Management Consulting Co., Ltd.
Room 1401, Dongfang Building, 1500# Century Ave.
Shanghai, 200122
CHINA

Re: K233477
Trade/Device Name: Cryo-straw (Type I, Type III);
Warming Kit (A-4ML, B-8ML);
Vitrification Kit (A-3ML, B-6ML)
Regulation Number: 21 CFR 884.6180
Regulation Name: Reproductive Media and Supplements
Regulatory Class: II
Product Code: MQL, MQK
Received: May 28, 2024

Dear Eva Li:

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.

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,

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)*
K233477

Device Name
Vitrification Kit (A-3ML, B-6ML)
Warming Kit (A-4ML, B-8ML)
Cryo-straw (Type I, Type III)

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

The Warming Kit is indicated for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.

The Cryo-straw is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain 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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Shandong Wego Ruisheng Medical Device Co., LTD.
No. 1 , Weigao Road, Torch High- tech Industrial Development Zone, Weihai, Shandong, China

510(K) Summary
K233477

1. Submitter

Shandong Wego Ruisheng Medical Device Co.,Ltd.
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Weihai, Shandong, China
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2. Date Prepared: July 1, 2024

3. Device

Trade/Proprietary Name:	Vitrification Kit (A-3ML, B-6mL) Warming Kit (A-4ML, B-8mL) Cryo-straw (Type I, Type III)
Common Name	Vitrification Cryopreservation Media
Regulation	21 CFR§ 884.6180
Regulation Name	Reproductive Media and Supplements,
Product Code	MQL (Media, Reproductive), MQK (Labware, Assisted Reproduction)
Classification	Class II
Classification panel	Obstetrics/Gynecology

4. Predicate Device

Vitrification Kit and Thawing Kit from Kitazato Corporation (K171748).

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

5. Device Description

The Vitrification Kit and Warming Kit are assisted reproduction technology (ART) media products for freezing and thawing oocytes (MII), pronuclear (PN) zygotes through Day 3

cleavage stage embryos, and blastocyst stage embryos.

There are two models for each Vitrification Kit and Warming Kit. The difference is the volume of the solutions in the kits. The solutions in the "A" model for each kit are in 1 ml vials, and the solutions in the "B" model are in 2 ml vials. Each model contains two sets of kit media.

The Vitrification Kit includes three sequential media components, Washing solution (WS), Equilibrium solution (ES), and Vitrification solution (VS), containing the cryoprotectants ethylene glycol, dimethyl sulfoxide, and sucrose. Using this methodology, the permeating cryoprotectants can replace water in the oocyte and PN through blastocyst stage embryos prior to vitrification and storage in liquid nitrogen.

The Warming Kit is composed of three media used sequentially for thawing and removing cryoprotectants from vitrified oocytes and PN through blastocyst stage embryos. The Warming Kit is composed of Thaw solution (TS), Diluent solution (DS), and Washing solution (WS).

All media in the Vitrification Kit and Warming Kit undergo aseptic filtration and are single-use only.

The Cryo-Straw is a single-use, sterile, cryopreservation storage device for holding and maintaining vitrified oocytes (MII) and pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos. There are two models for the Cryo-straws: Type I and Type III, and each has 5 colors: brown, orange, blue, red, green. The Cryo-straws are composed of a rod and sheath with a combined length of 132.5 mm. The Type I model has a flat slide and the Type III model has a curved slide for sample loading. The Cryo-straws are sterilized using gamma radiation.

6. Indication for Use

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

The Warming Kit is indicated for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.

The Cryo-straw is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.

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7. Substantial Equivalence Discussion

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

Table 1 Comparison of Characteristic

Comparison Item	Subject device K233477	Predicate Device K171748	Comparison
510(k) Number	K233477	K171748	
Device Name	Vitrification Kit (A-3ML, B-6mL) Warming Kit (A-4ML, B-8mL) Cryo-straw (Type I, Type III)	Vitrification Kit and Thawing Kit	NA
Indications for Use	The Vitrification Kit is indicated for use in the vitrification of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos. The Warming Kit is indicated for use in the thawing of vitrified oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos. The Cryo-straw is a cryopreservation storage device that is intended for use in vitrification procedures to contain and maintain vitrified oocytes (MII), pronuclear (PN)	Vit Kit® - Freeze (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. Vit Kit® - Thaw (Vitrification Thaw Kit) is intended for use in the thawing of oocytes (MII), pronuclear (PN) zygotes through day 3 cleavage stage embryos and blastocyst stage embryos.	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 devices are the same.

	zygotes through day 3 cleavage stage embryos, and blastocyst stage embryos.		
Component	Vitrification Media Thawing Media Cryopreservation storage device	Vitrification Media Thawing Media Cryotop Repro Plate 35 mm dish	**Different:** The components of the subject and predicate devices are not the same. Differences in device components do not raise different questions of safety and effectiveness (S&E).
Media Components			
Vitrification Formulation	Medium 199 HEPES Sodium bicarbonate Sodium pyruvate Gentamicin sulfate Ethylene glycol Dimethyl sulfoxide Sucrose	Medium 199 HEPES Ethylene glycol Dimethyl sulfoxide Trehalose Hydroxypropyl Cellulose 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.
Thawing Formulation	Medium 199 HEPES Sodium bicarbonate Sodium pyruvate Gentamicin sulfate Sucrose	Medium 199 HEPES Hydroxypropyl Cellulose Gentamicin Trehalose	**Different:** The formulations of the subject and predicate devices are not

			the same. Differences in device formulations do not raise different questions of safety and effectiveness (S&E).
Endotoxin	<0.25EU/mL	<0.25 EU/mL	Same
MEA	One-cell MEA: ≥80% embryos developed to expanded blastocyst within 96 hours	One-cell MEA: >80% embryos developed to expanded blastocyst within 96 hours	Similar
pH	7.2-7.4	7.2-7.6	Similar
Osmolarity (mOsm/kg)	ES: 1391-1590 (1:1 dilution) VS: 1430-1710 (1:3 dilution) TS: 1,650-2,170 DS: 850-925 WS: 265-295	ES: 2,300-2,800 VS: 4,900-6,000 TS: 1,600-2,000 DS: 830-1020 WS/BS: 240-300	**Different:** The subject device and predicate devices have differences in osmolality specifications. These differences in osmolality specifications do not raise different questions of S&E.
Sterilization Method	Aseptic Filtration	Aseptic Filtration	Same
Shelf-Life	6 months	1 year	**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
Storage Device			
Material Composition	PETG	ABS, polypropylene, stainless steel	**Different:** The materials of the subject and predicate devices are not the same. Differences in device materials do not raise different questions of S&E.
Design/ Vitrification Method	Closed vitrification system. The device consists of a rod and a sheath. The rod of Type I Cryo-straw has a flat slide and the Type III Cryo-straw has a curved slide, where the samples are loaded. After samples are loaded, the slide is inserted into the pre-cooled sheath to create a sealed closed system. The assembled device is stored in liquid nitrogen (LN).	Closed vitrification system. The devices are a two piece assembly comprised of a handle shaft attached to a film tip, where the samples are loaded, and a straw enclosure. After samples are loaded, the film tip is inserted into the pre-cooled straw to create a sealed closed system. The sealed device is stored in LN.	Similar
Device Dimension	Rod: 118 mm × 2.7 mm Slide: - Type I: 16 mm x 0.2 mm - Type III: 12 mm x 0.24 mm Sheath: 44 mm	Unknown	**Different:** The device dimension of the predicate devices

	- OD: 2.9 mm - ID: 1.95 mm		unknown. Differences in device dimension do not raise different questions of S&E.
Media Loading Volume	<0.5 microliter	Unknown	**Different:** The media loading volume of the predicate devices are unknown. Differences in media loading volume do not raise different questions of S&E.
Cooling Rate	Type I: 1,539℃/min Type III: 1,543℃/min	Cryotop CL: -3,000 °C/min Cryotop SC: -2,900 °C/min Cryotop US: -2,900 °C/min	**Different:** The cooling rates of the subject and predicate devices are not the same. Differences in cooling rates do not raise different questions of S&E.
Warming Rate	Type I : 21,430℃/min Type III: 21,385℃/min	Cryotop CL: 40,000 °C/min Cryotop SC: 42,000 °C/min Cryotop SC: 44,000 °C/min	**Different:** The warming rates of the subject and predicate devices are not the same. Differences in

			warming rates do not raise different questions of S&E.
Sterilization	Radiation, SAL 10^{-6}	Radiation, SAL 10^{-6}	Same
Single-Use	Yes	Yes	Same
MEA	One-cell MEA: ≥80% embryos developed to expanded blastocyst within 96 hours	One-cell MEA: ≥80% embryos developed to expanded blastocyst within 96 hours	Same
Endotoxin	<0.5 EU/device	<0.5 EU/device	Same
Shelf-Life	2 years	3 years	**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

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 represent a new intended use and the differences in technological characteristics do not raise different questions of safety and effectiveness.

8. Non-Clinical Performance Data:

Vitrification Kit and Warming Kit:

- Aseptic processing and validation testing that met the requirements of ISO 13408-1:2008/Amd1:2013 and ISO 13408-2:2018.
- Shelf-life testing was conducted to support a 6-month shelf-life for the subject devices through demonstration that the product specifications (shown below) were met at time 0 and after real-time aging:
  - pH per USP <791>: 7.2-7.4 for all solutions
  - Osmolality per USP <785>: see the table above for acceptance specifications

- Endotoxin per USP <85>: <0.25 EU/mL
- Mouse Embryo Assay (MEA): One-cell system: ≥80% embryos developed to expanded blastocyst at 96 hours
- Sterility per USP<71>: No microbial growth

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

Cryo-straw:

- The sterilization process and validation methods in accordance with ISO 11737-1:2018, ISO 11737-2:2019, and ISO 11137-3:2017. The sterilization assurance level of the subject device is 10^{-6}.
- Shelf-life testing was conducted to support a two-year shelf-life for the subject device through demonstration that the product specifications (shown below) were met at time 0 and after real-time aging or accelerated aging in accordance with ASTM F1980-16:
  - Cooling rate: (Type I:1,539°C/min; Type III:1,543°C/min)
  - Warming rate: (Type I :21,430°C/min; Type III:21,385°C/min)
  - Dimensional testing
  - Durability: No damage after 30 second immersion in liquid nitrogen
  - Liquid nitrogen penetration: No ingress after 24-hour immersion in liquid nitrogen
  - Endotoxin per USP<85: <0.5EU/device
  - Package integrity/Transportation Testing: Seal strength per F88/F88M-23 and dye penetration per ASTM F1929-23 following real-time aging and transportation conditioning device per ASTM D4169-22.
  - Tensile strength of rod and sheath
  - Mouse Embryo Assay (MEA): one-cell system: ≥80% embryos developed to expanded blastocyst at 96 hours

9. Conclusion

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