May 7, 2024

Wuhan Huchuang Union Technology Co., Ltd.
% Ivy Wang
Technical Manager
Shanghai Sungo Management Consulting Company Limited
14th Floor, 1500# Central Avenue
Shanghai, Shanghai 200122
CHINA

Re: K232493
Trade/Device Name: Embryo Real-time Incubator (TLS301),
Embryo Real-time Culture Dish (MC 2004)
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulatory Class: II
Product Code: MQG, MQK, MTX
Dated: April 7, 2024
Received: April 8, 2024

Dear Ivy Wang:

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, PhD
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)*
K232493

Device Name
Embryo Real-time Incubator (TLS301), Embryo Real-time Culture Dish (MC 2004)

Indications for Use *(Describe)*
The Embryo Real-time Incubator (TLS301) is intended to provide an environment with controlled temperature and mixed gas (CO2 and other gases) for the development of embryos. The Embryo Real-time Incubator (TLS301) has an integrated camera and optics for imaging and viewing embryos during incubation, for a maximum time of 120 hours.

The Embryo Real-time Culture Dish (MC 2004) is intended for preparing, storing and transferring human embryos. It is intended to be used only with the Embryo Real-time Incubator (TLS301).

Embryo Realtime 2S Software and Embryo Realtime 3E Software are optional software accessories for the Embryo Real-time Incubator (TLS301).

The Embryo Realtime 2S Software is intended to store, archive and transfer data. In addition, the Embryo Realtime 2S Software includes functions for managing models and performing calculations based on image data and embryo development parameters.

Embryo Realtime 3E Software is intended for viewing and recording embryo development events from images captured using the Embryo Real-time Incubator (TLS301). Embryo Realtime 3E Software includes a user annotation function for capturing information on embryo development parameters and a user-defined modeling function that allows the user to combine annotated information on embryo development parameters to aid in embryo selection.

Embryo Realtime 2S Software and Embryo Realtime 3E Software do not control any hardware components in the Embryo Real-time Incubator (TLS301). Embryo Realtime 2S Software and Embryo Realtime 3E Software are provided in different software package and must be used together.

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

K232493

I. Submitter Information

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Address: Building10, No.818 Gaoxin Avenue Wuhan Hubei 430206 China
Name of contact person: Zhan Yuanyuan
Tel: +86-13554695434
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II. Date Prepared

May 7, 2024

III. Subject Device Information

Device trade name: Embryo Real-time Incubator (TLS301), Embryo Real-time Culture Dish (MC 2004)
Common Name: Embryo Incubator
Regulation number: 21 CFR 884.6120
Regulation Name: Assisted Reproduction Accessories
Regulation class: II
Product code: MQG (Accessory, Assisted Reproduction), MQK (Labware, Assisted Reproduction), MTX (Microscope and Microscope Accessories, Reproduction, Assisted)

IV. Predicate Device

EmbryoScope+ (K173264) manufactured by Vitrolife A/S

The predicate device has not been subject to any design related recalls.

V. Device Description

The Embryo Real-time Incubator (TLS301) consists of the following components:

- Embryo Real-time Incubator, integrated with temperature control system, gas supply control system and time-lapse imaging system.
- Image capture software
- Workstation, composed of server and workstation software.
- Embryo Real-time Culture Dish (MC 2004)

The Embryo Real-time Incubator (TLS301) is a benchtop tri-gas (CO_2, N_2, and air) embryo incubator with a built-in microscope for time-lapse imaging intended to be used for the culture and monitoring of embryos used in Assisted Reproductive Technology (ART) procedures. It provides temperature control, gas control, and time-lapse imaging at multiple focal planes. The incubator chamber has the capacity to hold up to ten

Embryo Real-time Culture Dishes (MC 2004). Each chamber contains a heating plate to maintain chamber temperatures. Gas (CO_2, N_2, and air) is mixed in a mixing chamber and passed through a HEPA/VOC filter prior to delivery to the incubation chamber. The built-in microscope consists of an illumination unit (red LED, 635 nm) and an inverted microscope/camera unit. The imaging system is mobile and is controlled through moving guide rail to automatically position the camera to the designated culture plate/well. The camera can acquire images in multiple focal planes. The time-lapse imaging system in the incubator along with the image capture software capture time-lapse images of the embryos and transmit captured images to the computer for display and storage. The image capture software also reads the patient labels on the Embryo Real-time Culture Dish (MC 2004) and incorporates patient information into the imaging record.

The workstation includes a server and workstation software (Embryo Realtime 3E Software). It includes graphical user interface and receives and stores images. It also supports query, retrieval and display of the embryo images. The workstation software allows for manual annotation of the series of images obtained through time-lapse imaging into a user-defined model for the assessment of embryo's development. In addition, the server software (Embryo Realtime 2S Software), that does not include a graphical user interface, is designed to archive, transfer and store images of embryos from the time lapse incubator and performs user model management and calculations based on image data and user inputted embryo development parameters. The two software are used together.

The Embryo Real-time Culture Dish (MC 2004) is a single use, single-patient, polystyrene, radiation sterilized culture dish intended for preparing, storing, and transferring human embryos. It is intended to be used only with the Embryo Real-time Incubator (TLS301). It contains two types of wells: 3 wells for rinsing and handling the embryos before or after incubation and 16 wells for culturing the embryos during incubation. Each culture well is used to culture one embryo and a total of 16 embryos from a single patient can be cultured on one dish. The culture and rinsing wells have a volume of 30 μL and 50 μL, respectively. There is a central depression in the center of each culture well, where the embryo resides. The Embryo Real-time Culture Dishes (MC 2004) has a label area for unique identification of the culture dish.

VI. Indications for Use

The Embryo Real-time Incubator (TLS301) is intended to provide an environment with controlled temperature and mixed gas (CO2 and other gases) for the development of embryos. The Embryo Real-time Incubator (TLS301) has an integrated camera and optics for imaging and viewing embryos during incubation, for a maximum time of 120 hours.

The Embryo Real-time Culture Dish (MC 2004) is intended for preparing, storing and transferring human embryos. It is intended to be used only with the Embryo Real-time

Incubator (TLS301).

Embryo Realtime 2S Software and Embryo Realtime 3E Software are optional software accessories for the Embryo Real-time Incubator (TLS301).

The Embryo Realtime 2S Software is intended to store, archive and transfer data. In addition, the Embryo Realtime 2S Software includes functions for managing models and performing calculations based on image data and embryo development parameters.

Embryo Realtime 3E Software is intended for viewing and recording embryo development events from images captured using the Embryo Real-time Incubator (TLS301). Embryo Realtime 3E Software includes a user annotation function for capturing information on embryo development parameters and a user-defined modeling function that allows the user to combine annotated information on embryo development parameters to aid in embryo selection.

Embryo Realtime 2S Software and Embryo Realtime 3E Software do not control any hardware components in the Embryo Real-time Incubator (TLS301). Embryo Realtime 2S Software and Embryo Realtime 3E Software are provided in different software package and must be used together.

VII. Comparison of Intended Use and Technological Characteristics of the Subject and Predicate Devices

Attribute	Subject device (K232493)	Predicate device (K173264)	Comparison
Indications for Use	The Embryo Real-time Incubator (TLS301) is intended to provide an environment with controlled temperature and mixed gas (CO2 and other gases) for the development of embryos. The Embryo Real-time Incubator (TLS301) has an integrated camera and optics for imaging and viewing embryos during incubation, for a maximum time of 120 hours. The Embryo Real-time	The EmbryoScope+ incubator provides an environment with controlled temperature and gas concentrations (CO2 and O2) for the development of embryos at or near body temperature. Use of the EmbryoScope+ incubator is limited to five days (120 hr) covering the time from post insemination to day five of development. The EmbryoSlide+ culture dish is intended for preparing, storing, and transferring human	The indications for use statements for the subject and predicate devices are not identical; however, their intended uses are the same (i.e., time-lapse imaging of embryos maintained in a device-specific culture dish).

	Culture Dish (MC 2004) is intended for preparing, storing and transferring human embryos. It is intended to be used only with the Embryo Real-time Incubator (TLS301). Embryo Realtime 2S Software and Embryo Realtime 3E Software are optional software accessories for the Embryo Real-time Incubator (TLS301). The Embryo Realtime 2S Software is intended to store, archive and transfer data. In addition, the Embryo Realtime 2S Software includes functions for managing models and performing calculations based on image data and embryo development parameters. Embryo Realtime 3E Software is intended for viewing and recording embryo development events from images captured using the Embryo Real-time Incubator (TLS301). Embryo Realtime 3E Software includes a user annotation function for capturing information on embryo development parameters and a user-defined modeling function that allows the	embryos. The EmbryoSlide+ culture dish must be used together with the EmbryoScope+ incubator. The EmbryoViewer software is intended for displaying, comparing, storing, and transferring images generated by the EmbryoScope+ incubator. This software includes a user annotation function for capturing information on embryo development parameters as well as a user-defined modeling function, which allows the user to combine annotated information on embryo development parameters to aid in embryo selection. The EmbryoViewer software does not control any hardware components in the EmbryoScope+ incubator. The ES Server software is intended to store, archive and transfer data. In addition, this software includes functions for managing models and performing calculations based on image data and embryo development parameters. The EmbryoScope+ incubator, EmbryoViewer software, and ES Server software must be used	

	user to combine annotated information on embryo development parameters to aid in embryo selection. Embryo Realtime 2S Software and Embryo Realtime 3E Software do not control any hardware components in the Embryo Real-time Incubator (TLS301). Embryo Realtime 2S Software and Embryo Realtime 3E Software are provided in different software package and must be used together.	together to export embryo images from the EmbryoScope+ incubator. The EmbryoViewer software and ES Server software must be used together to analyze the embryo images.	
Incubator, integrated computer and microscopy system			
Culture dish capacity	10 dishes	15 dishes	**Different**
Heating mechanism	Heated aluminum container and lid	Direct heat transfer	**Different**
Temperature range	35-40 °C	36-39 °C	Similar
Temperature accuracy	± 0.2 °C	± 0.2 °C	Similar
CO2 accuracy	±0.1% for CO2 concentration at 6.0%, ±0.2% for other CO2 concentration	± 0.3 %	**Different**
O2 accuracy	±0.1% for O2 concentration at 5.0%, ±0.2% for other O2 concentration	± 0.5 %	**Different**
Recirculation rate	150ml ±7.5ml/min (full purification of gas volume every 6.3 min)	>100 L/h (full purification of gas volume every 6 min)	**Different**
Recovery time	CO2 (6%±0.3%) ≤90 seconds O2(5%±0.3%) ≤90 seconds when the load door is	CO2 (5% ± 0.3 %) <5 min O2 (5% ± 0.5 %) <3 min when the load door is closed after a 30-second	**Different**

	closed after a 15-second load door opening (single chamber)	load door opening	
Control of temperature and gas	Firmware	Firmware	Same
Computer	Integrated	Integrated	Same
Microscope	Inverted microscope	Inverted microscope	Same
Type of camera	Monochrome CMOS	Monochrome CMOS	Same
Magnification	20×	16×	**Different**
Focusing	Fully automated dish detection and embryo focusing	Fully automated dish detection and embryo focusing	Same
Numerical aperture	0.45	0.5	Similar
Number of pixels	2048 × 1088 pixels	2048 × 1088 pixels	same
Resolution	≥ 2.7 pixels per µm	3 pixels per µm	**Different**
Light source (for imaging)	Low-power red LED 635 nm	Low-power red LED 627 nm	Similar
Time-lapse system	Time-lapse imaging (Hoffman Modulation Contrast Objective). 10 Min cycle time for 11 focal planes	Time-lapse imaging (Hoffman Modulation Contrast Objective). 10 Min cycle time for 11 focal planes for up to 5 days	Same
Embryo Realtime 2S Software and Embryo Realtime 3E Software			
Image display	High-resolution time-lapse images of single embryos	High-resolution time-lapse images of single embryos	Same
Data handling	Export, storage and transfer of embryo data	Export, storage and transfer of embryo data	Same
Embryo annotation and data analysis	• Embryo annotation tools which assist the user in selecting embryos • Model designer	• Embryo annotation tools which assist the user in selecting embryos • Model designer • Model management • Data analysis using user-defined modeling function	**Different**
Incubation condition monitoring	Inspection of incubation details, such as temperature and gas conditions	Inspection of incubation details, such as temperature and gas conditions	Same
Embryo Real-time Culture Dish (MC 2004)			

General design	Optically clear culture dish with a lid	Optically clear culture dish with a lid	Same
Material	Polystyrene	Polystyrene	Same
Culture wells on the dish	16 wells for individual embryo incubation	16 wells for individual embryo incubation	Same
Rinsing wells in the dish	3 wells	4 wells	Different
Sterile	Yes	Yes	Same

As noted in the table above, the subject and predicate devices do not have identical indication for use statements; however, their intended use are the same (i.e., time-lapse imaging of embryos maintained in a device-specific culture dish). In addition, there are differences in the technological characteristics between the subject and predicate devices, including culture dish capacity, heating mechanism, gas recirculation rate, gas/temperature recovery time, gas accuracy specifications, microscope magnification, camera resolution, and number of dish rinsing wells. The technological differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

VIII. Summary of Non-clinical Performance

Non-clinical bench testing for the Embryo Real-time Incubator (TLS301) with the Embryo Realtime 2S Software and Embryo Realtime 3E Software was conducted to verify that the subject device met all design specifications, demonstrated their performance, and to demonstrate substantial equivalence to the predicate device. The following tests were conducted:

- Electrical safety testing per IEC 61010-1:2010 + A1: 2016 *Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements* and IEC 61010-2-010: 2019 *Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials*
- Electromagnetic compatibility testing per 2022 FDA Guidance - *Electromagnetic Compatibility (EMC) of Medical Devices* and IEC 60601-1-2:2020 *Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral Standard: Electromagnetic disturbances – Requirements and tests*
- Software validation was conducted in accordance with the 2023 FDA guidance "*Content of Premarket Submissions for Device Software Functions.*"
- Cybersecurity was evaluated per the 2023 FDA guidance "*Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."*
- Bench performance testing to evaluate that the device met all the specifications listed in the table in Section VII:
    - Temperature control performance to evaluate temperature stability under normal working, power-off and cold-start conditions, and heating and cooling times in different environments.

- Gas concentration performance to evaluate gas concentration stability under normal working, alarm, power-off and cold-start conditions and gas consumption over time.
- Microscope performance testing to evaluate light exposure safety of embryo (wavelength and intensity of illumination source, exposure time, time-lapse worst-case imaging simulation with mouse embryo assay), image quality, and auto-positioning and auto-focus functions.

- Performance testing conducted on the Embryo Real-time Culture Dish (MC2004) to support substantial equivalence to the predicate device:
  - Radiation sterilization and validation testing per ISO 11137-2: 2006 and the 2024 FDA guidance "*Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile Guidance for Industry and Food and Drug Administration Staff*".
  - Transportation simulation testing in accordance with ASTM D4169-22
  - Shelf-life testing (accelerated aging) per ASTM F1980:2016, including the following assessments:
    - Endotoxin testing per USP <85> and ANSI/AAMI ST72:2019. The testing demonstrated that the device met the specification of ≤0.5 EU/device.
    - Mouse embryo assay (MEA) per the 2021 FDA guidance document "Mouse Embryo Assay for Assisted Reproduction Technology Devices" before and after accelerated aging-
      The testing demonstrated that the device met acceptance criterion of "1-cell MEA ≥80% embryos developed to blastocyst in 96 hours."
    - Visual assessment for appearance of the product (transparent, smooth, no cracks, no scratches, no dust, no oil).
    - Package integrity testing after accelerated aging:
      - Dye penetration test per ASTM F1929-15
      - Peel strength testing per ASTM F88/F88M-21
      - Visual assessment per ASTM F1886/F1886M-16

IX. Conclusions

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