



May 22, 2025

Hua Yue Medical Technology Co., Ltd.
Zhenzhi Shi
R&D Director
First Floor, C2 building, No.11 Kaiyuan Road
Huangpu District, Guangzhou City, Guangdong Province
Guangzhou, 510530
CHINA

Re: K242684
Trade/Device Name: Harioculture TL-16 Time-lapse Incubator
Regulation Number: 21 CFR 884.6120
Regulation Name: Assisted Reproduction accessories
Regulatory Class: II
Product Code: MQG, MQK, MTX
Received: April 30, 2025

Dear Zhenzhi Shi:

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
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K242684

Device Name

Harioculture TL-16 Time-lapse Incubator

Indications for Use (Describe)

Harioculture TL-16 Time-lapse Incubator consists of the following devices with the following indications for use: Time-lapse Incubator provides an environment with controlled temperature and gas concentrations (CO₂ and O₂) or mixed gas (CO₂ and other gases) for the development of embryos at or near body temperature. Use of the Time-lapse Incubator is limited to five days (120 hr) covering the time from post insemination to day five of development. The Hariomed culture dish is intended for preparing, storing, and transferring human embryos. The Hariomed culture dish must be used together with the Time-lapse Incubator. The Harioculture-client software is intended for displaying, comparing, storing, and transferring images generated by the Time-lapse 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 Harioculture-client software does not control any hardware components in the Time-lapse Incubator. The Harioculture-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 Time-lapse Incubator, Harioculture-client software, and Harioculture-server software must be used together to export embryo images from the Time-lapse Incubator. The Harioculture-client software and Harioculture-server software must be used together to assist users to analyze the embryo images.

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 K242684

1. Submitter Information

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Phone: +86-020-34821111

Contact Person (Title): Shi Zhenzhi (R&D Director)

E-mail: register@huayueco.com

2. Date of Preparation: May 21, 2025

3. Subject Device Information

Device Trade Name:	Harioculture TL-16 Time-lapse Incubator
Common Name:	Time-lapse Embryo Incubator
Regulation Number:	21 CFR 884.6120
Regulation Name:	Assisted Reproduction Accessories
Product Codes:	MQG (Accessory, Assisted Reproduction), MQK (Labware, Assisted Reproduction), MTX (Microscope and Microscope Accessories, Reproduction, Assisted)
Regulatory Class:	II

4. Predicate Device Information

EmbryoScope+ (K173264) manufactured by Vitrolife A/S.

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

5. Device Description

Harioculture TL-16 Time-lapse Incubator consists of the following components:

- Time-lapse Incubator,
- Harioculture-server software,
- Harioculture-client software,
- Hariomed culture dish.

The Time-lapse Incubator is a benchtop 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 microscopy at multiple focal planes. This device can hold up to 16 culture dishes (Hariomed culture dish) in the culture cabin. The device can be connected to the capacity expansion module which in turn can also accommodate 16 culture dishes. The capacity expansion module is similar to the main incubator and provides the same culture capacity as the incubator host. However, it cannot be run independently and needs to be used together with the Incubator host. The incubator host includes the software to control the temperature, gas concentration, imaging as well as image display on the incubator screen. The culture dishes are placed in the culture slots on the turntable in

the Time-lapse Incubator. The culture slots provide direct heat transfer to the Hariomed culture dishes. The built-in microscope consists of an illumination unit (red LED, 630±5 nm) and an inverted microscope/camera unit. During image acquisition, turntable is rotated to position individual culture dishes on the microscopy system and image stacks are acquired for individual embryos in each culture dish.

The Time-lapse Incubator supports two gas control and culture modes:

- Self-mixed mode – Under the self-mixed gas culture mode, CO₂, and N₂ gases are supplied from medical grade gas cylinders. These gasses (CO₂, N₂ and re-flux gas) are mixed in a mixing chamber and passed through a HEPA/VOC filter prior to delivery to the culture cabin. This culture mode does not allow for humidification of the chamber (dry-culture mode).
- Pre-mixed mode – Under the pre-mixed gas culture mode, the gas is supplied from standard premixed medical gas cylinders. Pre-mixed gas passes through the HEPA/VOC filter and a humidification box to form a humidified gas which then enters the culture cabin. The humidification box is sterile, single-use component with a sterility assurance level (SAL) of 10⁻⁶ and a shelf-life of two years. The pre-mixed culture mode allows humidification of chamber (wet-culture mode).

The Hariomed culture dish is a single use, single-patient, polystyrene, radiation sterilized culture dish intended for preparing, storing, and transferring human embryos. The Hariomed culture dish is intended for use only with Harioculture TL-16 Time-lapse Incubator and includes two culture ponds. Each culture pond has eight microwells and a total of 16 embryos from a single patient can be cultured on one dish. Each dish includes four rinsing wells for rinsing and handling the embryos before or after incubation. The dishes have area for unique barcode labels that can be printed through the Harioculture-client software. The barcode labels provide patient identification information. The Hariomed culture dish has a sterility assurance level (SAL) of 10⁻⁶ and a shelf-life of two years.

The Harioculture-client software is intended for displaying, comparing, storing, and transferring images generated by the Time-lapse Incubator. The data that can be viewed using this software includes embryo images, incubation details, alarms, log files and other instrument parameters. This software also 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 Harioculture-client software does not control any hardware components in the Time-lapse Incubator.

The Harioculture-server software allows users to update and view common data. The server acts as the central unit, which stores data and controls the data flow to and from the connected devices. The server can be connected to multiple Time-lapse incubators and computers with the Harioculture-client software.

6. Indications for Use

Harioculture TL-16 Time-lapse Incubator consists of the following devices with the following indications for use:

Time-lapse Incubator provides an environment with controlled temperature and gas concentrations (CO₂ and O₂) or mixed gas (CO₂ and other gases) for the development of embryos at or near body temperature. Use of the Time-lapse Incubator is limited to five days (120 hr) covering the time from post insemination to day five of development.

The Hariomed culture dish is intended for preparing, storing, and transferring human embryos. The Hariomed culture dish must be used together with the Time-lapse Incubator.

The Harioculture-client software is intended for displaying, comparing, storing, and transferring images generated by the Time-lapse 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 Harioculture-client software does not control any hardware components in the Time-lapse Incubator.

The Harioculture-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 Time-lapse Incubator, Harioculture-client software, and Harioculture-server software must be used together to export embryo images from the Time-lapse Incubator. The Harioculture-client software and Harioculture-server software must be used together to assist users to analyze the embryo images.

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

The table below compares the intended use and technological characteristics of the subject and predicate device.

Device & Predicate Device(s):	Subject device -K242684	Predicate device – K173264	Comparison
Indications for Use	Harioculture TL-16 Time-lapse Incubator consists of the following devices with the following indications for use: Time-lapse Incubator provides an environment with controlled temperature and gas concentrations (CO₂ and O₂) or mixed gas (CO₂ and other gases) for the development of embryos at or near body temperature. Use of the Time-lapse Incubator is limited to five days (120 hr) covering the time from post insemination to day five of development. The Hariomed culture dish is intended for preparing, storing, and transferring human embryos. The Hariomed culture dish must be used together with the Time-lapse Incubator. The Harioculture-client software is intended for displaying, comparing, storing, and transferring images generated by the Time-lapse 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 Harioculture-client software does not control any hardware components in the Time-lapse Incubator. The Harioculture-server software is intended to store, archive and transfer data. In	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 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.	

	addition, this software includes functions for managing models and performing calculations based on image data and embryo development parameters. The Time-lapse Incubator, Harioculture-client software, and Harioculture-server software must be used together to export embryo images from the Time-lapse Incubator. The Harioculture-client software and Harioculture-server software must be used together to assist users to analyze the embryo images.	The EmbryoScope+ incubator, EmbryoViewer software, and ES Server software must be used 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			
Heating mechanism	Direct heat transfer	Direct heat transfer	Same
Culture dish capacity	16 dishes	15 dishes	Different
Temperature range	35-40° C	36-39°C	Similar
Temperature accuracy	± 0.1 °C	± 0.2°C	Similar
CO ₂ accuracy	± 0.1% for CO ₂ concentration rate setting 5.0%, ± 0.2% for other CO ₂ concentration rate setting	± 0.3 %	Similar
O ₂ accuracy	± 0.1% for O ₂ concentration rate setting 5.0%, ±0.2% for O ₂ concentration rate setting other than 5.0%	± 0.5 %	Similar
Gas control mechanism	Individual gases (CO ₂ and N ₂ in Self-mixed mode) and pre-mixed gases (Pre-mixed mode)	Individual gases (CO ₂ and N ₂)	Different
Recirculation rate	Incubator host only: > 49 L/h (full purification of gas volume every 2min) in self-mixed mode Incubator host with expansion module : > 24.5L/h (full purification of gas volume every 4min) in self-mixed mode	>100 L/h (full purification of gas volume every 6 min)	Different
Recovery times	CO ₂ (5% ± 0.2 %) <3.5 min, O ₂ (5% ± 0.2 %) <3.5 min, when the load door is closed after a 30-second load door opening	CO ₂ (5% ± 0.3 %) <5 min, O ₂ (5% ± 0.5 %) <3 min, when the load door is closed after a 30-second load door opening	Different
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	20x	16x	Different
Focusing	Fully automated dish detection and embryo focusing	Fully automated dish detection and embryo focusing	Same
Numerical aperture	0.45	0.5	Different
Number of pixels	1920 × 1200 pixels	2048 x 1088 pixels	Different

Resolution	>3 pixels per μm	3 pixels per μm	Same
Light source (for imaging)	Single red LED (630nm $\pm$ 5nm)	Low-power red LED 627 nm	Different
Illumination per image	15-30ms	<0.02 seconds	Different
Total light exposure /embryo/day	<32 seconds	<40 seconds	Different
Light dosage	Total light dose during 5-Day (120 h) incubation < 52 J/m ²	Total light dose during 5-Day (120 h) incubation of 65.2 J/m ² .	Different
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
Image display	High-resolution time-lapse images of single embryos	High-resolution time-lapse images of single embryos	Same
Incubation condition monitoring	Inspection of incubation details, such as temperature and gas conditions	Inspection of incubation details, such as temperature and gas conditions	Same
Workstation and Server/Embryo viewer			
Embryo annotation and comparison	Embryo annotation tools which assist the user in selecting embryos, Model designer, Model management, Data analysis using user-defined modeling function	Embryo annotation tools which assist the user in selecting embryos, Model designer, Export of data	Similar
Image export, storage and transfer	Handled by Server software	Handled by ES server	Same
Model management	Handled by Server software	Handled by ES server	Same
Data calculation	Handled by Server software	Handled by ES server	Same
Culture Dish			
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 on the dish	4 wells	4 wells	Same
Culture well volume	2 μL	1.5 μL	Different
Rinsing well volume	30 μL	30 μL	Same
Sterility	Yes	Yes	Same
MEA	More than 80% expanded blastocysts after 96 hrs.	More than 80% expanded blastocysts after 96 hrs.	Same
Endotoxin	<0.5 EU/device	<20 EU/device	Different

As noted in the table above, the subject and predicate devices do not have identical indications 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, gas recirculation rate, gas/temperature recovery time, gas accuracy specifications, microscope magnification, camera resolution etc. The technological differences between the subject and predicate devices do not raise different questions of safety and effectiveness.

8. Summary of Non-clinical Testing

The following studies were conducted on the Time-lapse Incubator, Harioculture-client software, Harioculture-server software to verify that the subject device met all design specifications, demonstrated their performance, and to support substantial equivalence to the predicate device:

- Electrical safety testing per IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- Electromagnetic compatibility (EMC) testing per IEC 60601-1-2:2014+A1:2020, *Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*, IEC TS 60601-4-2: 2024, *Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems* and 2022 FDA Guidance - *Electromagnetic Compatibility (EMC) of Medical Devices*.
- Software verification and validation per the 2023 FDA Guidance Document, “*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 7 for incubator along with the capacity expansion module in both self-mixed (dry- culture) and pre-mixed (wet-culture) modes of operation:
 - Gas concentration control testing and gas flow control testing to ensure that gas levels, gas flow rates and gas recovery rates in cabin meet design specifications.
 - Temperature control testing to ensure that incubator temperature conditions were within defined ranges and stable over time.
 - Imaging testing to evaluate light exposure safety of embryo (wavelength, exposure time, time-lapse worst-case imaging simulation with mouse embryo assay), image quality and resolution, auto-positioning, and auto-focus functions
 - Relative humidity control testing to ensure that the humidity levels in cabins meet design specifications.
 - Performance testing for the HEPA/VOC filter including particle filtration efficiency and VOC removal efficiency testing.
- The following studies were conducted on the Hariomed culture dish to support substantial equivalence to the predicate device:
 - Radiation sterilization and validation testing per ISO 11137-2: 2013+A1:2022 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 per ASTM D4169-23 followed by package integrity testing
 - Shelf-life testing (accelerated aging) per ASTM F1980:2021, including the following assessments
 - 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.”
 - Endotoxin testing per USP <85>. The testing demonstrated that the device met the specification of ≤0.5 EU/device

- Visual inspection for appearance of the product (culture dish and lid are colorless, transparent, with smooth surface, no oil, no impurities, no scratches, no bubbles, and no deformations).
- Package integrity testing after accelerated aging:
 - Bubble test per ASTM F2096-11
 - Peel strength testing ASTM F88/F88M-21
- The following studies were conducted on the Hariomed humidification box to support the sterility and use-life of the humidity control system to the Time-lapse Incubator
 - Radiation sterilization and validation testing per ISO 11137-2: 2013+A1:2022 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 per ASTM D4169-23 followed by package integrity testing.
 - Continuous humidification testing to support a 30-day use-life.
 - Shelf-life testing (accelerated aging) per ASTM F1980:2021, including the following package integrity assessments after aging
 - Dye penetration testing per ASTM F1929-15
 - Peel strength testing ASTM F88/F88M-21

9. Conclusion

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.