June 17, 2026

Hua Yue Medical Technology Co., Ltd.
Zhenzhi Shi
R&D Director
First Floor, C2 Bldg., #11 Kaiyuan Rd.
Huangpu District
Guangzhou, Guangdong 510530
CHINA

Re: K253333
Trade/Device Name: Assisted Reproduction Laser System (Model ILS-400M)
Regulation Number: 21 CFR 884.6200
Regulation Name: Assisted Reproduction Laser System
Regulatory Class: II
Product Code: MRX
Received: May 15, 2026

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: 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)*
K253333

Device Name
Assisted Reproduction Laser System (Model ILS-400M)

Indications for Use *(Describe)*
The Assisted Reproduction Laser System (Model ILS-400M) is for use in assisted reproduction procedures to ablate or thin the zona pellucida of an embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis (blastomeres). The device can also be used on blastocyst stage embryos for biopsy of trophectoderm cells for pre-implantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary – K253333

1. Submitter Information

Company Name: Hua Yue Medical Technology Co., Ltd.
Address: First Floor, C2 building, No.11 Kaiyuan Road, Huangpu District, Guangzhou City, Guangdong Province, 510530, P.R. China
Phone: +86-020-34821111
Contact Person (Title): Shi Zhenzhi (R&D Director)
E-mail: register@huayueco.com

2. Date of Preparation: June 16, 2026

3. Subject Device Information

Trade/Proprietary Name: Assisted Reproduction Laser System (Model ILS-400M)
Common Name: Assisted Reproduction Laser System
Regulation Number: 21CFR 884.6200
Regulation Name: Assisted Reproduction Laser System
Product Code: MRX
Review Panel: Obstetrics/Gynecology
Regulatory Class: II

4. Predicate Device Information

510(k) Number: K141434
Trade/Proprietary Name: Saturn 5 Laser System

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

5. Device Description

The Assisted Reproduction Laser System (Model ILS-400M) is composed of a laser control unit (including Laser Control Module, Optical Fiber and the Power Adapter), movement control unit (including Movement Control Module, Power Adaptor), Mirror Module, Laser Objective (40x and 20x) and Assisted Reproduction Laser System Control Software. The system has been designed to be fitted to commercially available inverted microscopes and is also used with a PC and camera to provide an optical system and means of firing the laser. A Foot Switch for firing the laser is available as an optional extra device component.

This Assisted Reproduction Laser System (Model ILS-400M) delivers two lasers: the ablation laser and the pilot laser. Both laser beams are launched from the end of a fiber optic and collimated by an achromatic collimator. The Assisted Reproduction Laser System Control software controls the movement of the laser, fires the laser and allows the user to take measurements and generate and store images.

The Assisted Reproduction Laser System (Model ILS-400M) includes a single-pulse mode and multi-pulse mode. The multi-pulse mode enables users to ablate a series of holes along a set of pre-determined paths. The preset lines can be either straight or curved. After drawing the shooting path,

users can adjust the laser drilling spacing by adjusting the drilling density. The multi-pulse mode is as safe as the single-pulse mode. Users can choose the usage mode according to their application scenarios.

6. Indications for Use

The Assisted Reproduction Laser System (Model ILS-400M) is for use in assisted reproduction procedures to ablate or thin the zona pellucida of an embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis (blastomeres). The device can also be used on blastocyst stage embryos for biopsy of trophectoderm cells for pre-implantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.

7. Substantial Equivalence Discussion

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

Parameter	**Subject device** **Assisted Reproduction Laser System (Model ILS-400M)** **K253333**	**Predict device** **Saturn 5 Laser System** **K141434**	**Comparison**
Indications for Use	The Assisted Reproduction Laser System (Model ILS-400M) is for use in assisted reproduction procedures to ablate or thin the zona pellucida of an embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis (blastomeres). The device can also be used on blastocyst stage embryos for biopsy of trophectoderm cells for pre-implantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.	For use in assisted reproduction procedures to ablate or thin the zona pellucida of an oocyte or embryo to facilitate assisted hatching or recovery of cells for pre-implantation genetic diagnosis (blastomeres). The device can also be used on blastocyst stage embryos for biopsy of trophectoderm cells for pre-implantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.	The indications for use for the subject and predicate devices differ, as the subject device is to be used to ablate or thin the zona pellucida of an embryo, while the predicate is to be used for the same uses for oocytes or embryos. This difference does not raise new questions of safety or effectiveness.
System configuration	•Laser control unit •Movement control unit •Mirror Module •Laser Objective(40X,20X) •Assisted Reproduction Laser System Control Software	• Laser control unit • 40X objective • Microscope adapters • Mirror module • Motor module (Active version only) •Laser application software	The subject and predicate devices have similar components, but differences exist (e.g., Objective magnification)

	• Camera (optional) • Foot switch (optional)	• Camera (optional) • Foot switch (optional)	However, these differences do not raise different questions of safety and effectiveness.
Operating Modes	Active Mode – The direction and path of the laser beam is computer-controlled; embryo is stationary.	Fixed Mode – The direction of the laser beam is fixed; user manually guides embryo. Active Mode – The direction and path of the laser beam is computer-controlled; embryo is stationary.	The subject device only has active mode capability. However, the differences do not raise different questions of safety and effectiveness.
Laser Modes	Single-Pulse mode: Allows a single ablation of the target （Active Mode） Multi-Pulse mode: Allows to ablate a series of holes for biopsy procedures （Active Mode）	Single Pulse: Allows a single ablation of the target (Fixed Mode and Active Mode) Biopsy Mode: Allows to ablate a series of holes for biopsy procedures (Active Mode only)	Same
Laser Specifications	λ = 1480 nm Power 400 mW Pulse length 5-2000 µs	λ = 1480 nm Power 400 mW Pulse length 5-2000 µs	Same
Laser Classification	Class 1	Class 1	Same
Microscope Compatibility	Compatible with various models of inverted microscopes.	Compatible with various models of inverted microscopes.	Same
Laser Firing Mechanism	Mouse; foot switch	Mouse; foot pedal	Similar
Hole Size Indicator	Yes	Yes	Same

The indications for use of the subject and predicate device are similar, with the subject device specifying use for only embryos. Since the subject and predicate device intended use populations overlap (i.e., both are used for ablating or thinning the zona pellucida of an embryo), no new questions of safety or effectiveness are raised.

The subject and predicate devices have similar technological features, including laser specification, firing mechanism, laser modes, and microscope compatibility. However, as shown in the table above, there are technological differences between the subject and predicate device, including differences in available operating modes and system configurations. The different technological characteristics of the subject device, as compared to the predicate device, do not raise different questions of safety and effectiveness and were sufficiently evaluated in the non-clinical testing outlined below.

8. Summary of non-clinical Performance Testing

The following performance tests were conducted on the Assisted Reproduction Laser System (Model ILS-400M):

Laser Performance Testing

Laser Performance Testing in accordance with the 2004 FDA guidance document "Assisted Reproduction Laser Systems – Class II Special Controls Guidance Document for Industry and FDA Staff.

Electrical Safety and Electromagnetic Compatibility (EMC)

- Electrical safety
  - IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
  - AAMI ES60601-1:2005/AMD1:2012, AAMI ES60601-1:2005/AMD2:2021
- Electromagnetic compatibility (EMC)
  - IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020
  - ANSI AAMI IEC60601-1-2:2014+A1:2021
  - IEC TS 60601-4-2: 2024
- Laser Safety Testing

Both the pilot laser and ablation laser are classified as Class I in accordance with IEC 60825-1:2014.

Software and Cybersecurity

Software verification and validation testing that met the requirements of the FDA Guidance Document, "Content of Premarket Submissions for Device Software Functions" issued on June 2023.

Cybersecurity was evaluated per the 2023 FDA guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions".

9. Conclusion

The results of the performance testing described above demonstrate that Assisted Reproduction Laser System (Model ILS-400M) is as safe and effective as the predicate device and supports a determination of substantial equivalence.