July 2, 2021

Hamilton Thorne, Inc.
Donald Fournier
Director, Regulatory Affairs & Quality Assurance
100 Cummings Center, Suite 465E
Beverly, MA 01915

Re: K202241
Trade/Device Name: LYKOS™ Assisted Reproduction Laser with Dynamic Targeting System (DTS)
Regulation Number: 21 CFR§ 884.6200
Regulation Name: Assisted Reproduction Laser System
Regulatory Class: II
Product Code: MRX
Dated: June 3, 2021
Received: June 4, 2021

Dear Donald Fournier:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

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)*
K202241

Device Name
LYKOS™ Assisted Reproduction Laser with Dynamic Targeting System (DTS)

Indications for Use *(Describe)*
The LYKOS Assisted Reproduction Laser with Dynamic Target System (DTS) is intended for in vitro fertilization (IVF) laboratory use in assisted reproduction procedures to ablate a small, tangential hole or thin the zona pellucida of select IVF embryos to facilitate assisted reproduction hatching procedures and to biopsy trophectoderm cells from blastocyst stage embryos for purposes of preimplantation genetic diagnosis or screening.

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
K202241

LYKOS™ Assisted Reproduction Laser with Dynamic Targeting System (DTS)

Submitter Hamilton Thorne, Inc.
100 Cummings Center, Suite 465E
Beverly, MA 01915
Tel: (978) 921-2050
Fax: (978) 921-0250

Contact Person Donald Fournier
Director, Regulatory Affairs & Quality Assurance
100 Cummings Center, Suite 465E
Beverly MA 01915
Tel: (978) 921-2050 Ext. 1726
Fax: (978) 921-0250
dfournier@hamiltonthorne.com

Date Prepared June 30, 2021

Subject Device

Trade Name:	LYKOS™ Assisted Reproduction Laser with Dynamic Targeting System (DTS)
Common Name:	Assisted Reproduction Laser System
Regulation Name:	Assisted Reproduction Laser System
Regulation Number:	21 CFR § 884.6200
Product Code:	MRX (System, Assisted Reproduction Laser)
Regulatory Class:	Class II

Predicate Device

510(k) Number:	K141434
Device Name:	Saturn 5™ Laser System
Manufacturer:	Research Instruments Ltd

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

Device Description

The LYKOS with DTS is comprised of hardware, software and firmware. Hardware components include a laser control unit, communication cable, optional foot pedal, microscope mount(s) and a 40x objective. Fully integrated within the objective is the laser, a rotating mirror frame and motors that rotate the mirror and control the direction of the laser beam. The objective can be mounted on most commercially available inverted microscopes. The laser hardware interfaces with a computer and camera, providing a live image of the objective's field of view on the computer monitor. The system also records images and videos of the laser procedures.

The system includes three laser modes: Clinical, Multipulse, and Validation. The Clinical Mode includes laser settings recommended for zona thinning and embryo hatching procedures. The Multipulse Mode allows the use of a series of laser pulses and is intended for trophectoderm biopsy procedures. The Validation Mode is intended to validate the proper operation of the laser including RED-i and laser alignment.

Targeting of the laser beam (i.e., either aiming its direction or plotting its ablation path) may be performed in two modes: fixed direction or DTS. In the fixed direction mode of operation, the direction of the beam remains fixed and the embryo is manually guided to the laser by the user. In the DTS Mode, the position of the embryo remains fixed and the direction of the laser is computer-controlled, navigating a user defined plot as drawn on the computer monitor. The system can be programmed to aim and fire the laser anywhere in the field of view or along a user-defined ablation path.

In both Manual and DTS modes, because the laser operates in the invisible infrared wavelength (λ = 1460 nm), to aim and visually verify the position of the laser beam at all times prior to firing, the laser is concentrically aligned with a visible red LED beam (RED-i). Through an automated mapping and verification system using the X-Y coordinates of the computer monitor, the laser can be aimed and an ablation path plotted and verified by the user prior to each use.

Indications for Use

The LYKOS Assisted Reproduction Laser with Dynamic Target System (DTS) is intended for in vitro fertilization (IVF) laboratory use in assisted reproduction procedures to ablate a small, tangential hole or thin the zona pellucida of select IVF embryos to facilitate assisted reproduction hatching procedures and to biopsy trophectoderm cells from blastocyst stage embryos for purposes of preimplantation genetic diagnosis or screening.

Substantial Equivalence Comparison

A comparison of the indications for use and technological characteristics of the subject and predicate devices are summarized in the table below:

Parameter	Subject Device LYKOS DTS	Predicate Device SATURN 5 – K141434	Comparison
Indications for Use	The LYKOS Assisted Reproduction Laser with Dynamic Target System (DTS) is intended for in vitro fertilization (IVF) laboratory use in assisted reproduction procedures to ablate a small, tangential hole or thin the zona pellucida of select IVF embryos to facilitate assisted reproduction hatching procedures and to biopsy trophectoderm cells from blastocyst stage embryos for purposes of preimplantation genetic diagnosis or screening.	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 preimplantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.	**Different:** The indications for use statements for the subject and predicate devices are different. Both the subject and predicate devices are for use in ablating or thinning the zona pellucida (ZP) to facilitate assisted hatching of embryos and can also be used for trophectoderm biopsy. However, the predicate device is indicated for additional uses beyond those of the subject device, including ablation/thinning of the ZP of oocytes and blastocyst collapse prior to vitrification, These differences represent a more limited use of the subject device and do not represent a new intended use. Therefore, the indented uses are the same.

System Configuration	• Laser control unit • 40X objective • Microscope adapters • Mirror module • Motor module • Laser application software • Computer user-interface • Camera • Foot switch (optional)	• Laser control unit • 40X objective • Microscope adapters • Mirror module • Motor module (Active version only) • Laser application software • Computer user-interface • Camera • Foot switch (optional)	**Different:** The subject and predicate are comprised of different components. The differences in device components do not raise different questions of safety and effectiveness (S&E).
Operating Modes	Fixed Direction – The direction of the laser beam is fixed; user manually guides embryo. DTS – The direction and path of the laser beam are 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.	**Similar**
Laser Modes	Clinical Mode: Allows a single ablation of the target (Fixed Mode and DTS Mode) or a series of ablations (DTS Mode) Multipulse Mode: Allows the use of a series of laser pulses for biopsy procedures (Fixed Mode only) Validation Mode: For validation of proper operation of the laser (Fixed Mode and DTS 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)	**Different:** The subject and predicate devices have different laser modes. The differences do not raise different questions of S&E.
Laser Specifications	λ = 1460 nm Power: 3-300 mW Pulse length: 0.1 to 3.0 ms	λ = 1480 nm Power 400 mW Pulse length 5-2000 μs	**Different:** The subject and predicate devices have differences in laser wavelength, power and pulse lengths. These differences do not raise different questions of S&E.
Alignment Indicator	Yes - RED-i	Yes -Pilot laser	**Similar**
Laser Classification (U.S CFR 1040.10)	Class I	Class I	**Same**
Microscope Compatibility	Compatible with various models of inverted microscopes.	Compatible with various models of inverted microscopes.	**Same**
Laser Firing Mechanism	Mouse; foot pedal	Mouse; foot pedal	**Same**
Hole Size Indicator	Yes	Yes	**Same**

As noted in the table above, there are differences in the indications for use statements and technological features 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 features do not raise different questions of safety and effectiveness.

Summary of Performance Testing

The following performance data was provided in support of the substantial equivalence determination:

- 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." Additional testing included the following:

- Validation of the RED-i target alignment feature
- Validation of the accuracy and precision of DTS single-pulse across the field of view
- Validation of the accuracy and precision of DTS multiple-pulse (linear or curved plots) across the field of view

- Electrical Safety and Electromagnetic Compatibility (EMC) Testing in accordance with:
  - Electrical Safety Testing: IEC 61010-1:20117; IEC 60825-1:2014
  - EMC Testing: IEC 61326-1:2013
- Software and Cybersecurity:
  - Software documentation in accordance with the 2005 FDA guidance document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" to support device software with a moderate level of concern.
  - Cybersecurity information in accordance with the 2014 FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."
- Reprocessing: Validation testing conducted in accordance with the 2015 FDA guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

Conclusion

The results of the testing described above demonstrate that the subject device is substantially equivalent to the predicate device.