March 25, 2020

Vitrolife GmbH
Susanne Schweitzer
Manager QA/QC/RA
Dr.-Pauling-Str.9
Bruckberg, Bavaria 84079
GERMANY

Re: K192008
Trade/Device Name: NaviLase, LaserShot M
Regulation Number: 21 CFR 884.6200
Regulation Name: Assisted Reproduction Laser System
Regulatory Class: II
Product Code: MRX
Dated: February 19, 2020
Received: February 24, 2020

Dear Susanne Schweitzer:

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,

Monica D. Garcia, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192008

Device Name
NaviLase, LaserShot M

Indications for Use *(Describe)*
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 preimplantation 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.

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510(k) Summary
K192008

Submitter

Company Name	Vitrolife GmbH
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Contact person

Name	Susanne Schweitzer
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Date Prepared	March 22, 2020

Subject device

Trade name	NaviLase, LaserShot M
Common Name	Assisted Reproduction Laser System
Regulation Name	Assisted Reproduction Laser System
Regulation Number	884.6200
Product code	MRX (System, Assisted Reproduction Laser)
Regulatory Class	II

Predicate device

510(k) number	K141434
Device name	Saturn 5™ Laser Systems
Manufacturer	Research Instruments Ltd

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

Device Description

This submission includes two assisted reproduction laser systems, the LaserShot M and the NaviLase. The LaserShot M is a static laser system where the embryo is moved to the laser by moving the stage of the microscope. The LaserShot M components include a laser module (1.48 µm infrared diode laser, class 1M), laser adapter to connect to the microscope, mirror block, laser objective (25X), USB camera, EyeWare Software, and an optional target pointer and footswitch. The NaviLase includes the same components as the LaserShot M, but also includes a motion module and a motion controller. These additional components allow the NaviLase to work in two modes, fixed and dynamic. In fixed mode, the NaviLase operates similarly to the LaserShot M. In dynamic mode, the laser can be directed to any location within the field of view. In addition, dynamic mode allows automated laser firing along a user-defined path (straight line, arc, etc.). The EyeWare software controls the device components, operates the laser, and takes images and records videos of embryo undergoing laser procedures. The software determines how many holes are drilled along this line and controls/restricts laser firing parameters to

minimize localized heating of the embryo during these procedures. These laser devices have been designed to be fitted to compatible inverted microscopes.

Indications for Use

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 preimplantation diagnosis procedures, and blastocyst collapse prior to vitrification procedures.

Substantial Equivalence Comparison

	Subject Device LaserShot M/NaviLase K181776	**Predicate Device Saturn 5 K141434**	**Comparison**
Indications for Use	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 preimplantation 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	**Different:** 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 represent a new intended use. Therefore, the indented uses are the same.
System configuration	• Laser unit • Target pointer • 25X objective • EyeWare software • Installation adapters • Mirror module • Motion control unit (NaviLase Only) • Digital camera • Foot switch	• Control unit (laser unit) • 40X objective • Mirror module • Motor module (Active version only) • RI Viewer software • Installation adapters • Control unit • Camera • Foot switch	**Different:** The subject and predicate devices have similar components, but differences exist (e.g., objective magnification, target pointer, etc.). These differences do not raise different questions of Safety and Effectiveness (S&E).

Modes of Action	LaserShot M – Fixed laser system where the user moves the sample to the target area. NaviLase – Operates in fixed (similar to LaserShot M) and dynamic modes. The dynamic mode allows the user to move the laser target to the sample within the field of view on the display screen.	Fixed mode and active mode. Active mode allows the user to move the laser within the field of view.	**Same**
Laser Details	1.48 µm diode laser Class 1M laser	1.48 µm diode laser Class 1 laser	**Different**: The class of lasers are different. This difference does not raise different questions of S&E.
Energy delivered	140 mW and 200 mW	400 mW	**Different:** The subject device has a lower energy output. This difference does not raise different questions of S&E.
Maximum Pulse Length	10 ms	2ms	**Different:** The subject device has a longer maximum pulse length than the predicate device. This difference does not raise different questions of S&E.
Multi-Pulse Mode	Yes – NaviLase dynamic mode allows user to ablate a series of holes along a set, pre-determined path.	Yes – active version allows user to ablate a series of holes along a set, pre-determined path.	**Same**
Hole Size Indicator	Yes	Yes	**Same**
Laser firing mechanism	Mouse or foot pedal	Mouse or foot pedal	**Same**
Microscope Compatibility:	Compatible with various models of inverted microscopes	Compatible with various models of inverted microscopes	**Same**
Hole Size Indication:	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.

Performance Testing

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

- Reprocessing: Validation testing conducted in accordance with the 2015 FDA guidance document, "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

- Electrical Safety and Electromagnetic Compatibility Testing:

    - Electrical Safety Testing: IEC 60601-1:2005/AMD1:2012

    - EMC Testing: IEC 61326-1:2012

- 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 minor level of concern.

    - Cybersecurity information in accordance with the 2014 FDA guidance document "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices."

- Laser performance testing: Testing was performed in accordance with recommendations in Section 7 of FDA's 2004 guidance document "Assisted Reproduction Laser Systems – Class II Special Controls Guidance Document for Industry and FDA Staff." Additional testing included the following:

    - Compatibility of the devices with different microscope systems.

    - Target pointer alignment validation to demonstrate that the center of the target pointer marker was aligned with the center of the ablation laser beam.

    - Validation of NaviLase dynamic targeting within the field of view.

    - Validation of the NaviLase dynamic targeting system's ability to complete automated ablations under specific treatment modes (e.g., hole, hatching, thinning, and trophectoderm).

Conclusion

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