August 9, 2018

LENSAR, Inc.
Keith Peck
Director, Quality Assurance
2800 Discovery Drive, Suite 100
Orlando, FL 32826

Re: K181430
Trade/Device Name: LENSAR Laser System - fs 3D (LLS-fs 3D)
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: May 31, 2018
Received: June 6, 2018

Dear Keith Peck:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely yours,

Bradley S. Cunningham -A

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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)*

K181430

Device Name

LENSAR Laser System - fs 3D (LLS-fs 3D)

Indications for Use *(Describe)*

The LENSAR Laser System – fs 3D (LLS-fs 3D) with Streamline™ is an ophthalmic surgical laser indicated for use:

- in the creation of an anterior capsulotomy;
- in patients undergoing surgery requiring laser-assisted fragmentation of the cataractous lens;
- in the creation of full and partial thickness single-plane and multi-plane arc cuts/incisions in the cornea;
- in patients undergoing ophthalmic surgery or other treatments requiring pocket cuts/incisions in the cornea; and
- in the creation of a corneal flap in patients undergoing treatment requiring initial lamellar resection of the cornea.

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

This 510(k) Summary has been prepared in accordance with the requirements of 21 CFR 807.92.

1.0 SUBMITTER INFORMATION

The submitter of this 510(k) Summary is:

Company:

LENSAR, Inc.
2800 Discovery Drive, Suite 100
Orlando, FL 32826

Contact Person:

Keith Peck
(888) 575-6412 (Office)
(407) 386-7228 (Fax)

Summary Preparation Date: May 31, 2018

2.0 DEVICE INFORMATION

Trade/Proprietary Name:	LENSAR Laser System - fs 3D (LLS-fs 3D)
Common/Usual Name:	Ophthalmic Femtosecond Laser
Classification Name(s):	Ophthalmic Femtosecond Laser (21 CFR 886.4390)
Product Code(s):	OOE
Review Panel:	Ophthalmic
Regulatory Class:	II

3.0 PREDICATE DEVICE

The legally marketed (predicate) device to which LENSAR is claiming substantial equivalence to is:

510(k) Number	Device Name	Manufacturer
K173346	LENSAR Laser System – fs 3D (LLS-fs 3D)	LENSAR, Inc.

4.0 DEVICE DESCRIPTION

The LENSAR Laser System - fs 3D (LLS-fs 3D) with Streamline™ is a medical device for use in ophthalmic surgery. The device utilizes a pulsed laser that can be used to cut a precision capsulotomy in the anterior lens capsule, to fragment the cataractous lens for removal during cataract surgery, and to create full and partial thickness single-plane and multi-plane arc cuts/ incisions in the cornea, each of which may be performed either individually or consecutively during the same procedure. The device is also intended for use in the creation of pocket cuts/ incisions in the cornea in patients undergoing ophthalmic surgery, and in the creation of a corneal flap in patients undergoing treatment requiring initial lamellar resection of the cornea, each of which may only be performed individually.

Use of the laser provides automated precision control of the size of the capsular opening; the type and parameters of laser fragmentation treatment within the lens; the size, architecture, and location of full thickness incisions within the cornea; the size, architecture, location, depth, and quantity of partial thickness incisions within the cornea; and the size, architecture, and depth of pocket and flap cuts.

The LENSAR Laser System – fs 3D (LLS-fs 3D) with Streamline™ includes the integration with pre-op analysis devices, automated Iris Registration with automatic cyclorotation adjustment, IntelliAxis-C™ (corneal) and IntelliAxis-L™ (lens) markers for simple alignment of Toric IOLs as well as treatment planning tools for precision-guided laser treatments.

5.0 INDICATIONS FOR USE

The LENSAR Laser System – fs 3D (LLS-fs 3D) with Streamline™ is an ophthalmic surgical laser indicated for use:

- in the creation of an anterior capsulotomy;
- in patients undergoing surgery requiring laser-assisted fragmentation of the cataractous lens;
- in the creation of full and partial thickness single-plane and multi-plane arc cuts/incisions in the cornea;
- in patients undergoing ophthalmic surgery or other treatments requiring pocket cuts/ incisions in the cornea; and
- in the creation of a corneal flap in patients undergoing treatment requiring initial lamellar resection of the cornea.

6.0 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

All elements of the proposed device remain unchanged from that cleared under K173346 except for the following technological difference:

- introduction of a new elliptical-shaped Patient Interface Device (PID) Kit which can be used as an alternate to the currently cleared PID for use with all indications except for the indications related to corneal pockets and flaps;
- a software change to ensure that Limbus detection is not impacted by the change in dimensions of the elliptical PID as mentioned above;
- replacing the machined Poly methyl methacrylate (PMMA) contact lens of the Curved Contact PID (as cleared in K173346) with a molded PMMA contact lens to allow for a more cost-effective and easier manufacturing process.

A software change unrelated to the requested change for the elliptical-shaped PID is a speed-up of the Iris Registration function and a slight expansion of the cyclorotation range over which the Iris Registration can be used, both without compromising safety and effectiveness.

7.0 PERFORMANCE DATA

The following performance data were undertaken in support of the substantial equivalence determination.

Performance Evaluation of the New Elliptical PID Modification:

Verification and validation testing were completed to demonstrate that the proposed device performance complies with specifications and requirements identified for the LENSAR Laser System – fs 3D. Each function and/or feature was verified through unit testing and system testing by means of the appropriate test case or test specification. The unit/system verification test reports provide the test cases, expected results for each test case, and the actual results obtained. All criteria for this testing were met and the results demonstrate that the LENSAR System with the new elliptical PID meets all performance specifications and requirements. The objectives defined in the validation plan were achieved according to the validation results. The software on the proposed LLS-fs 3D System has been updated in support of the changes outlined above.

Performance data supporting substantial equivalence is summarized as follows:

- An analysis of IOP rise as a result of the new elliptical PID was completed. A study was performed using porcine eyes, comparing the new elliptical PID to LENSAR's existing PID (already pre-market cleared). The results show the new proposed elliptical PID was consistent with (as it relates to IOP pressure rise) LENSAR's existing PID.
- An analysis of eye stability during surgery with the new elliptical PID as compared to LENSAR's current PID (already pre-market cleared) was performed. The results show that after the application of the suction, the minimum force necessary to detach the porcine eye from the suction ring was comparable to that of LENSAR's existing PID.
- An analysis of the potential to have corneal folds as a result of the new elliptical PID as compared to LENSAR's existing PID (already pre-market cleared) was assessed. Using OCT images, no visible folds were noted.
- An analysis of the impact of the new elliptical PID on the Iris Registration and Limbus detection functions was performed. The analysis incorporated images of eyes with the elliptical PID and showed that all specifications of the Iris Registration and the Limbus Detection functions were achieved.
- A review of the hazard analysis of all potential hazards to the patient, surgeon and other system operators was performed to consider all changes to the proposed LLS-fs 3D device. The hazard analysis demonstrates that all potential hazards have acceptable levels of probability/severity characteristics.

In all cases, the test results showed that the new elliptical PID meets the performance specifications and requirements. The comparison shows that the proposed LENSAR Laser System – fs 3D with the new elliptical PID is substantially equivalent to the LENSAR Laser System – fs 3D (LLS-fs 3D) (K173346).

The minor differences between the additional LENSAR device feature and the predicate device do not raise any new questions of safety or effectiveness.

Biocompatibility Testing:

Biocompatibility evaluations of materials coming in contact with the patient or patient fluid path in the LENSAR Laser System – fs 3D (LLS-fs 3D) were conducted in accordance with national/ international recognized standards.

The only difference between the new elliptical PID and the currently approved PID is a slight dimensional change in the suction ring portion of the PID. No materials changes have been made as a result of this change. Because of this and the Biocompatibility risk evaluation for the new elliptical PID Kits no new biocompatibility testing was deemed necessary.

As mentioned earlier, the PMMA contact lens that is part of the Curved Contact PID (currently machined) is changing to a molded PMMA contact lens. The new part was evaluated to ensure materials used were biocompatible and the relevant biocompatibility testing completed. Based on this testing (cytotoxicity, irritation and sensitization) no issues were found and all testing passed.

The PID Ring Arm is multi-use and is sterilized by autoclaving. There were no changes to the material or assembly of the PID Ring Arm as part of this submission and thus remains unchanged from prior device files.

Software Verification and Validation Testing:

A complete software verification and validation testing was conducted covering all cited changes and updates since the prior clearance (K173346), and documentation was provided as recommended by FDA's "*Guidance for Industry and FDA Staff, Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury to the patient or operator.

Summary of Clinical Studies:

The addition of the elliptical PID for use with the LENSAR Laser System did not require clinical performance data to demonstrate substantial equivalence to the predicate device.

8.0 CONCLUSIONS

The activities used to evaluate the LENSAR Laser System – fs 3D (LLS-fs 3D) and the information provided in this 510(k) submission do not identify any new issues of safety or effectiveness.

Based on the above supportive information, the proposed LENSAR Laser System – fs 3D (LLS-fs 3D) with the new elliptical PID and molded PMMA curved contact PID are substantially equivalent with respect to safety and effectiveness and indication for use as cleared in the LENSAR Laser System – fs 3D (LLS-fs 3D) predicate device (K173346).