March 2, 2018

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

Re: K173346
  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, HQC
  Dated: January 22, 2018
  Received: January 23, 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 -S

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
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.

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

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.  
Contact Person: Keith Peck  
2800 Discovery Drive, Suite 100  
Orlando, FL 32826  
(888) 575-6412 (Office)  
(407) 386-7228 (Fax)

Summary Preparation Date: March 1, 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)  
Phacofragmentation System (21 CFR 886.4670) 
Product Code(s): OOE; HQC 
Review Panel: Ophthalmic 
Regulatory Class: II

3.0 PREDICATE DEVICE

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

<table>
<thead>
<tr>
<th>510(k) Number</th>
<th>Device Name</th>
<th>Manufacturer</th>
</tr>
</thead>
<tbody>
<tr>
<td>K141476</td>
<td>WaveLight® FS200 Laser System</td>
<td>Alcon Laboratories, Inc.</td>
</tr>
</tbody>
</table>

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™ corneal and capsule marking 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 K171337 except for the following technological differences:

- addition of a new indication for use in patients undergoing ophthalmic surgery or other treatments requiring pocket cuts/incisions in the cornea;
- addition of a new indication for the creation of a corneal flap in patients undergoing treatment requiring initial lamellar resection of the cornea;
- introduction of a new curved contact Patient Interface Device (PID) Kit for use with the new indication of corneal pockets and corneal flaps;
- addition of Ethylene Oxide (EO) as an alternative sterilization method to Gamma radiation sterilization for the sterilization of the PID; and
- The Windows Operating System was changed from Windows 7 (32-bit) to Windows 10 (64-bit) as Windows 7 (32-bit) is going obsolete.
7.0 PERFORMANCE DATA

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

Performance Evaluation of the Corneal Pockets and Corneal Flaps Feature:

Verification and validation testing were completed to demonstrate that the proposed device performance complies with specifications and requirements identified for the LENSAR use in corneal pockets and corneal flaps. 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 corneal pockets and corneal flaps feature 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:

- The accuracy of the depth of the pocket and flap was tested using a porcine *ex vivo* eye model. The depth of the pocket and flap were measured using an optical coherence tomographer over various depths and compared to the intended depth. The study showed that the achieved depth was well within the established requirements for depth for both the pocket and flap.

- An analysis of the parallelism of the bed for both the created pocket and flap, respectively, was tested using a porcine *ex vivo* eye model. The study consisted of using the laser to cut a pocket and flap at various depths and measuring by means of an OCT. The achieved depth on several points of both the tangential and sagittal planes was measured and compared to the intended depth. The study showed that the achieved depth at several points of both the tangential and sagittal planes (i.e., parallelism) was well within the specification of the measured depth for both the pocket and flap.

- Evaluation (from a previous study) of the effect of the laser partial thickness incisions on endothelial cells of *ex vivo* eyes showed that the laser method results in no loss of endothelial cell density when a sufficiently large residual corneal bed is maintained.

- An analysis of IOP rise as a result of the new curved contact PID was completed. A study was performed using porcine eyes, comparing the new curved contact PID to LENSAR’s existing PID (already pre-market cleared) and to other applanating PIDs commercially available. The results show the new proposed curved contact PID was consistent with (as it relates to IOP pressure rise) other applanating PIDs that are commercially available.

- An analysis of eye stability during surgery with the new curved contact 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 higher for the curved contact PID versus that of LENSAR’s existing PID.

- 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. Specifically, an eye safety analysis was conducted. The retinal burn hazard analysis for the addition of corneal pockets and flaps showed no increase in hazard.

- For both the pocket and flap an assessment of the incision quality was conducted comprised of the following:
  - Ease of opening at the entrance to the pocket and flap,
  - Ease of separation of the incision layers, and
  - Smoothness of the bed surface was acceptable.

The study consisted of using the laser to cut a pocket at various depths in porcine eyes. A board certified ophthalmic surgeon, using standard instruments, was asked to grade (Yes/No) the acceptability for each of the factors above. The entire test was re-done for the corneal flap. The results showed that, in the judgement of the surgeon, each of the factors was consistent with that of the predicate device.

In addition, using donor eyes, the same surgeon compared the bed smoothness of both the pocket and the flap created by the proposed device to that of the predicate device. Again, the results showed that, in the judgement of the surgeon, the bed smoothness was consistent with that of the predicate device.

- An analysis of the potential to have corneal folds as a result of the new curved contact PID as compared to a commercially available applanating PID was assessed. Using OCT images, no visible folds were noted.

In all cases, the test results showed that the added features meet the performance specifications and requirements. The comparison shows that the proposed LENSAR Laser System – fs 3D is substantially equivalent to the WaveLight® FS200 Laser System (K141476) for the indication of use in the creation of pockets and flaps.

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.

As part of the new indication sought in this submission, a new PID Kit (curved contact PID Kit) is required. The only difference between this new curved contact PID Kit and that which was detailed and cleared in prior device files is the addition of a curved contact lens that is bonded to
the suction ring allowing for good suction and eye stability over the entire cornea while ensuring a good consistent quality laser cut in the cornea for the new indication. This new curved contact PID Kit is sterilized via EO (ethylene oxide).

Based on the biocompatibility risk evaluation for the curved contact PID Kits, and the fact that the PID Kit touches the mucous membrane for approximately less than 5 minutes, the following testing was required: cytotoxicity, irritation, and sensitization. These tests were performed by an outside nationally recognized laboratory using Good Laboratory Practices. All tests passed.

The PID Interface Arm is multi-use and is sterilized by autoclaving. There were no changes to the material or assembly of the PID Interface 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 (K171337), 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 corneal pockets and corneal flaps indications for use to 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) is substantially equivalent with respect to safety and effectiveness and indication for use as cleared in the K141476 predicate device (WaveLight® FS200 Laser System).