May 5, 2017

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

Re: K170576
   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: February 24, 2017
   Received: February 27, 2017

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Denise L. Hampton -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
Device Name
LENSTAR Laser System - fs 3D (LLS-fs 3D)

Indications for Use (Describe)

The LENSTAR Laser System - fs 3D (LLS-fs 3D) is intended for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, laser phacofragmentation, and the creation of 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.

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)

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

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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510(k) SUMMARY

This 510(k) Summary document 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:  
April 21, 2017

2.0 DEVICE NAME

Trade/Proprietary Name:  
LENSAR Laser System – fs 3D (LLS-fs 3D)

Common/Usual Name:  
LENSAR Laser System (LLS)

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(S)

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

<table>
<thead>
<tr>
<th>510(k) Number</th>
<th>Device</th>
<th>Date Cleared</th>
</tr>
</thead>
<tbody>
<tr>
<td>K143010 (Primary)</td>
<td>LENSAR Laser System – fs 3D (LLS-fs 3D)</td>
<td>03/20/2015</td>
</tr>
<tr>
<td>K152453</td>
<td>LENSAR Laser System – fs 3D (LLS-fs 3D)</td>
<td>10/15/2015 (Clearance for use of Nidek OPD Scan Topographer)</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
In 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. 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; as well as the size, architecture of incisions within the cornea, and depth of arcuate incisions. 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 marking for simple alignment of Toric IOLs as well as corneal treatment planning tools for precision guided laser treatments.

5.0 INDICATIONS FOR USE

The LENSAR Laser System - fs 3D (LLS-fs 3D) is intended for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, laser phacofragmentation, and the creation of 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.

6.0 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

All elements of the proposed device remain unchanged from that cleared in the legally marketed (predicate) devices except for:

- the addition of the Topcon Aladdin and OCULUS Pentacam® HR and Pentacam® AXL topographers for use with the Iris Registration feature of the LLS-fs 3D.
- an additional routine to the Iris Registration function that is intended to allow the algorithm to identify the cyclotorsion angle by way of increased robustness to pupil center drift and gaze direction.
- updated software to support improved user interaction and overall experience.

7.0 PERFORMANCE DATA

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

Performance Evaluation of the Iris Registration Feature

Verification and validation testing were completed to demonstrate that the device performance complies with the previously defined specifications and requirements identified for the predicate LENSAR Laser System. In addition to the verification of the three (3) new topographers, the Nidek OPD Scan Topographer data was re-run as part of the verification to demonstrate the Iris Registration results were substantially equivalent to its previous cleared specifications and requirements. All criteria were met and the results demonstrate that all performance specifications and requirements for the changes to the Iris Registration function and adding the
Topcon Aladdin, OCULUS Pentacam® HR and Pentacam® AXL topographers as validated topographers for use with the Iris Registration feature of the LLS-fs 3D have been met.

The software on the proposed LLS-fs 3D System has been updated in support of the changes outlined above.

<table>
<thead>
<tr>
<th>Iris Registration Comparison Results</th>
<th>Results Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topographer</strong></td>
<td>Algorithm Determines the Correct Cyclotorsion Angle</td>
</tr>
<tr>
<td>i-Optics Cassini</td>
<td>≥ 98.97%</td>
</tr>
<tr>
<td>Nidek OPD Scan</td>
<td>≥ 98.52%</td>
</tr>
<tr>
<td>Topcon Aladdin</td>
<td>≥ 97.17%</td>
</tr>
<tr>
<td>OCULUS Pentacam® HR</td>
<td>≥ 97.50%</td>
</tr>
<tr>
<td>OCULUS Pentacam® AXL</td>
<td>≥ 98.33%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Iris Registration Success Rates for i-Optics Cassini Topographer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Result</strong></td>
</tr>
<tr>
<td>Correct Cyclotorsion Angle</td>
</tr>
<tr>
<td>Cannot Determine an Angle</td>
</tr>
<tr>
<td>Incorrect Cyclotorsion Angle</td>
</tr>
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<tr>
<th>Iris Registration Success Rates for Nidek OPD Scan Topographer</th>
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<tbody>
<tr>
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<td>Correct Cyclotorsion Angle</td>
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<td>Cannot Determine an Angle</td>
</tr>
<tr>
<td>Incorrect Cyclotorsion Angle</td>
</tr>
</tbody>
</table>

The above tables of comparison results have been updated for the addition of the Topcon Aladdin, OCULUS Pentacam® HR and Pentacam® AXL topographers. Additionally, it has been updated for previously approved devices after re-running the respective data sets through the additional routine to the Iris Registration function, which resulted in slight changes to the expected percentages.
Summary of Clinical Studies

The addition of the Iris Registration changes and Topcon Aladdin, OCULUS Pentacam® HR and Pentacam® AXL topographers for use with the Iris Registration feature of the LENSAR Laser System does not change the indication for use. Thus, clinical performance data to demonstrate substantial equivalence was not required for this product change.

8.0 CONCLUSIONS

Based on the above supportive information, the proposed LENSAR Laser System - fs 3D (LLS-fs 3D) with the Iris Registration changes and the addition of the validated Topcon Aladdin, OCULUS Pentacam® HR and Pentacam® AXL topographers for use with the Iris Registration feature is substantially equivalent with respect to technological characteristics and indication for use as the legally marketed predicate device.