DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 24, 2017

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

Re: K171337/S002
Trade/Device Name: LENSAR Laser System – fs 3D (LLS-fs 3D)
Regulation Number: 21 CFR 886.4390, 886.4670
Regulation Name: Ophthalmic laser
Regulatory Class: Class II
Product Code: OOE, HQC
Dated: June 16, 2017
Received: June 19, 2017

Dear Keith Peck:

This letter corrects our substantially equivalent letter of August 10, 2017.

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 (DICE) 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 (DICE) 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,

Denise L. Hampton -S

for Malvina 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)*
K171337

Device Name
LENSAR Laser System – fs 3D (LLS-fs 3D)

Indications for Use *(Describe)*
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.

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 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: May 5, 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:

510(k) Number	Device	Date Cleared
K170576 (Primary)	LENSAR Laser System – fs 3D (LLS-fs 3D) (Iris Registration and i-Optics Cassini, Nidek OPD Scan, Pentacam® HR and AXL, and Topcon Aladdin Topographers)	05/05/2017
K112098	LENSAR Laser System – fs 3D (LLS-fs 3D) (Intended for use in cataract surgery includes anterior capsulotomy and laser phacofragmentation, each of which may be performed either individually or consecutively during the same procedure.)	10/19/2011
K123859	LENSAR Laser System – fs 3D (LLS-fs 3D) (Intended for use in cataract surgery includes 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.)	03/27/2013

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. 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 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) 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:

- an update to the software that allows for a modification to the current capsulotomy procedure that will place laser marks, using standard pre-operative data, onto the lens capsule as part of the capsulotomy to identify the astigmatic axis as prescribed by the surgeon. The modification allows the user to place two small protuberances/alignment marks created by the laser on the capsular rim on an axis that is defined by the surgeon using pre-operative data already received by the LENSAR Laser System from one of the cleared topographers or as entered by the surgeon.

7.0 PERFORMANCE DATA

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

Performance Evaluation of the Capsular IntelliAxis Feature:

Verification and validation testing were completed to demonstrate that the proposed device performance complies with specifications and requirements identified for the LENSAR Capsular IntelliAxis (aka IntelliCap) feature. 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 Capsular IntelliAxis 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.

Specifically, a study using porcine eyes was undertaken to (a) demonstrate the effectiveness and ease of use of the Capsular IntelliAxis feature as compared to K170576 (use of topographic measurements in pre-operative data entry) and K123859 (Arcuate Incisions) and (b) establish the substantial equivalence of the safety profile comparing the biomechanical strength for the LENSAR laser capsulotomy with alignment marks to that of the standard LENSAR laser capsulotomy cleared by FDA under 510(k) K112098.

The results show that the alignment marks are visible intraoperatively and, therefore, effective in helping surgeons to align the Toric IOL marks along the axis of astigmatism. Furthermore, the tensile test study demonstrates that the capsular rim for capsulotomy with alignment marks or nubs is substantially equivalent in elongation and tensile strength (ability to elongate and resistance to tearing under a radial force) to the standard capsulotomy with no alignment marks. Further, the accuracy of the requirements of the Capsular IntelliAxis feature was validated. The minor differences between the proposed LENSAR device feature and the predicate device do not raise any new questions of safety or effectiveness.

Summary of Clinical Studies

The addition of Capsular IntelliAxis feature of the LENSAR Laser System does not change the indication for use. 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 Capsular IntelliAxis feature is substantially equivalent with respect to safety and effectiveness and indication for use as cleared in the predicate laser file (K112098, K123859, and K170576).