



Food and Drug Administration
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October 15, 2015

LENSAR, Inc.
c/o Mohinder Merchea, OD, Ph.D., MBA
VP, Clinical & Regulatory Affairs
2800 Discovery Drive, Suite 100
Orlando, FL 32826

Re: K152453

Trade 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: September 5, 2015
Received: September 15, 2015

Dear Dr. Merchea:

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" (21CFR 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,


Deborah L. Falls -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

510(k) Number (if known)

K152453

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 is submitted in accordance with the requirements of 21 CFR 807.92.

I. SUBMITTERSubmitter:

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

Contact Person:

Mohinder Merchea
888-536-7271 (Office)
407-386-7228 (Fax)

Summary Preparation Date: August 28, 2015

II. DEVICE

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

Common or Usual Name: LENSAR Laser System

Classification Name(s): Ophthalmic Laser (21 CFR 886.4390),
Phacofragmentation System (21 CFR 886.4670)

Regulatory Class: II

Product Code(s): OOE; HQC

III. PREDICATE DEVICE(S)

<u>510(k) Number</u>	<u>Date Cleared</u>	<u>Device</u>
K143010	03/20/2015	LENSAR Laser System – fs 3D (LLS-fs 3D)

This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The LENSAR Laser System - fs 3D (LLS-fs 3D) 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 phaco fragmentation treatment within the lens; as well as the size, architecture of incisions within the cornea, and depth of arcuate incisions.

V. 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.

The indication for use of the subject device is unchanged from that of the predicate device.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

All elements of the proposed laser system **remain unchanged** from that cleared in K143010 with the addition of the validation of the Nidek OPD Scan Topographer for use with the Iris Registration feature of the LLS-fs 3D.

VII. 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 LENSAR Iris Registration feature. All criteria were met and the results demonstrate that the LENSAR Iris Registration feature meets all performance specifications and requirements. The evaluation specifically addressed performance of the Nidek OPD Scan Topographer as a validated topographer for use with the Iris Registration feature of the LLS-fs 3D.

Iris Registration Comparison Results		
Description	Nidek OPD Scan Topographer	i-Optics Cassini Topographer
Algorithm determines the correct cyclotorsion angle	≥ 99.26%	≥ 97.44%
Algorithm cannot determine an angle	≤ 0.74%	≤ 2.56%
Algorithm determines an incorrect cyclotorsion	≤ 1.81 * 10 ⁻³ %	≤ 1.81 * 10 ⁻³ %

Clinical Studies:

This additional feature does not change the Indication for Use. Thus no clinical evaluations are required as part of this submission.

VIII. CONCLUSIONS

Based on the above supportive documentation, it is the opinion of the Company that the subject LENSAR Laser System - fs 3D (LLS-fs 3D) is substantially equivalent with respect to technological characteristics and indication for use as cleared in the predicate laser file (K143010).