December 21, 2018

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

Re: K182795
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: September 28, 2018
Received: October 1, 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

Bradley S. Cunningham -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)*
K182795

Device Name
LENSAR Laser System - 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;
- in the creation of a corneal flap in patients undergoing treatment requiring initial lamellar resection of the cornea;
- in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; and
- in the creation of partial thickness single-plane radial cuts/incisions in 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.
2800 Discovery Drive, Suite 100
Orlando, FL 32826

Contact Person:

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

Summary Preparation Date: December 21, 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
K181430	LENSAR Laser System – fs 3D (LLS-fs 3D) (for use in radial cuts/incisions)	LENSAR, Inc.
K141476	WaveLight® FS200 Laser System (for use in tunnels for corneal ring segments)	Alcon Laboratories, Inc.

4.0 DEVICE DESCRIPTION

The 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, in the creation of a corneal flap in patients undergoing treatment requiring

initial lamellar resection of the cornea, and in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments, each of which may only be performed individually. Additionally, the device is also intended for use in the creation of partial thickness single-plane radial cuts/incisions in the cornea which may be performed individually or consecutively with arcuate incisions.

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, flap, and tunnel cuts.

The 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;
- in the creation of a corneal flap in patients undergoing treatment requiring initial lamellar resection of the cornea;
- in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; and
- in the creation of partial thickness single-plane radial cuts/incisions in the cornea

6.0 COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

All elements of the proposed device remain unchanged from that cleared under K181430 except for the following technological difference:

- addition of a new indication for use in patients undergoing surgery or other treatments requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; and
- addition of a new indication for the creation of partial thickness single-plane radial cuts/incisions in the cornea.

Other changes unrelated to the requested change for the addition of the new indications are as follows:

- allowing arcuate incisions that are currently cleared to be completed with the curved contact patient interface device (PID) that is already cleared;
- the ability to manually adjust the location of the capsulotomy without compromising the safety limits to the iris that already exist; and
- the ability to fragment the lens closer to the anterior capsule only within the boundaries of the capsulotomy diameter.

The following table provides a comparative between the proposed LLS-fs 3D laser device with the addition of the new indications and the predicate laser devices.

Table 1: Summary of Technological Characteristics

Characteristics	Proposed Device LLS-fs 3D Laser System 510(k) K182795	Predicate Device (Radial Cuts/Incisions) LLS-fs 3D Laser System 510(k) K181430 Cleared: 08/09/2018	Predicate Device (Tunnels for Corneal Ring Segments) WaveLight FS200 Laser System 510(k) K141476 Cleared: 09/30/2014
Indication 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; • in the creation of a corneal flap in patients undergoing treatment requiring initial lamellar resection of the cornea;	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; • in the creation of a corneal flap in patients undergoing treatment requiring initial lamellar resection of the cornea.	The WaveLight FS200 Laser System is an ophthalmic surgical laser indicated for use: • In the creation of a corneal flap in patients undergoing LASIK surgery or other surgery or treatment requiring initial lamellar resection of the cornea. • In patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments. • In the creation of a lamellar cut/resection of the cornea for lamellar keratoplasty. • In the creation of a penetrating cut/incision for penetrating keratoplasty and for corneal harvesting. • In patients undergoing ophthalmic surgery or other treatment requiring arcuate cuts/ incisions in the cornea. • In patients undergoing ophthalmic surgery or other treatment requiring pocket cuts/ incisions in the cornea.

Table 1: Summary of Technological Characteristics			
Characteristics	**Proposed Device** **LLS-fs 3D Laser System** **510(k) K182795**	**Predicate Device** **(Radial Cuts/Incisions)** **LLS-fs 3D Laser System** **510(k) K181430** **Cleared: 08/09/2018**	**Predicate Device** **(Tunnels for Corneal Ring Segments)** **WaveLight FS200 Laser System** **510(k) K141476** **Cleared: 09/30/2014**
	• in patients undergoing surgery or other treatment requiring initial lamellar resection of the cornea to create tunnels for placement of corneal ring segments; and • in the creation of partial thickness single-plane radial cuts/incisions in the cornea.		
Operating Principle	Photodisruption and plasma mediated ablation	Photodisruption and plasma mediated ablation	Photodisruption and plasma mediated ablation
Lens Fragmentation Removal	Provided by commercially available separate system of ultrasound; irrigation/ aspiration	Provided by commercially available separate system of ultrasound; irrigation/ aspiration	Provided by commercially available separate system of ultrasound; irrigation/ aspiration
Class/ Product Code/ Regulation	Class II/ OOE/ 886.4390	Class II/ OOE/ 886.4390	Class II/ OOE/ 886.4390
Patient Contact Portion of Device	Disposable polycarbonate/ silicone patient interface accessory; suction ring assembly	Disposable polycarbonate/ silicone patient interface accessory; suction ring assembly	Disposable patient contact consumable accessory; suction ring assembly and applanating cone.
Sterilization Method (patient interface accessory)	Gamma irradiation (not including Curved Contact PID) or Ethylene Oxide (EO)	Gamma irradiation (not including Curved Contact PID) or Ethylene Oxide (EO)	Ethylene Oxide (EO)
Laser Type	Yb:YAG	Yb:YAG	Nd:Glass*
Wavelength	1030 nm	1030 nm	1030 nm
Pulsing	Mode-locked	Mode-locked	Mode-locked
Mode	Fundamental (TEM00)	Fundamental (TEM00)	Fundamental (TEM00)
Pulse Duration	1.5 $x10^{-12}$ sec	1.5 $x10^{-12}$ sec	0.35 x 10^{-12} sec
Repetition Rate	20-80 kHz, adjustable	20-80 kHz, adjustable	200 kHz
Maximum Pulse Energy	15 µJ	15 µJ	2.4 µJ
Maximum Peak Power	9 MW	9 MW	7 MW

Table 1: Summary of Technological Characteristics			
Characteristics	**Proposed Device** **LLS-fs 3D Laser System** **510(k) K182795**	**Predicate Device** **(Radial Cuts/Incisions)** **LLS-fs 3D Laser System** **510(k) K181430** **Cleared: 08/09/2018**	**Predicate Device** **(Tunnels for Corneal Ring Segments)** **WaveLight FS200 Laser System** **510(k) K141476** **Cleared: 09/30/2014**
Biometrics	Scheimpflug Camera-based Imaging System with 3D Confocal Structured Illumination (3D-CSI)	Scheimpflug Camera-based Imaging System with 3D Confocal Structured Illumination (3D-CSI)	Opto-Mechanical referencing
Beam Targeting and Delivery	Computer-controlled scanner with F-theta lens	Computer-controlled scanner with F-theta lens	Computer-controlled scanner with F-theta lens
Photodisruptive Fluence Threshold in Lens Tissue	4 J/cm^2	4 J/cm^2	3 J/cm^2*
Intended Use for Iris Registration Feature	• System provides a means to assist the surgeon during anterior segment ophthalmic surgical procedures, to make an incision. • Using standard pre-operative clinical data, together with surgeon-driven, onscreen templates and guides, the System provides graphical assistance to the surgeon as desired during the surgery. • The system utilizes surgeon confirmation at each step for planning and positioning of guidance for incision placement. • The ocular rotation difference between the upright position (as observed during preoperative measurements) and the supine position (as observed during the surgical event) is determined either by manually marking the eye in the upright position and allowing the surgeon to line up	• System provides a means to assist the surgeon during anterior segment ophthalmic surgical procedures, to make an incision. • Using standard pre-operative clinical data, together with surgeon-driven, onscreen templates and guides, the System provides graphical assistance to the surgeon as desired during the surgery. • The system utilizes surgeon confirmation at each step for planning and positioning of guidance for incision placement. • The ocular rotation difference between the upright position (as observed during preoperative measurements) and the supine position (as observed during the surgical event) is determined either by manually marking the eye in the upright position and allowing the surgeon to line up	• Not Applicable.

Table 1: Summary of Technological Characteristics			
Characteristics	**Proposed Device** **LLS-fs 3D Laser System 510(k) K182795**	**Predicate Device (Radial Cuts/Incisions)** **LLS-fs 3D Laser System 510(k) K181430 Cleared: 08/09/2018**	**Predicate Device (Tunnels for Corneal Ring Segments) WaveLight FS200 Laser System 510(k) K141476 Cleared: 09/30/2014**
	the pre-marked eye in the upright position to that of the supine position by way of software reticules, or by the System's ability to analyze and match iris features between images acquired in each position.	the pre-marked eye in the upright position to that of the supine position by way of software reticules, or by the System's ability to analyze and match iris features between images acquired in each position.	
Intended Use for the Cataract Density Imaging Feature	• The imaging system of the LENSAR Laser System finds lens surfaces in order to correctly place pulses into the lens. Upon finding the lens surfaces, the imaging system also determines the location and degree of the nuclear cataract within the lens. The surgeon then has the ability to pick from a variety of fragmentation patterns as the surgeon sees fit. Additionally, the pattern itself can be altered in size and thereby the number of shots as the surgeon sees fit. • LENSAR Laser System provides a mechanism for the doctor to change the size and type of pattern as the surgeon sees fit. For convenience, the System is also provided with an optional mechanism for intra-operatively matching the nuclear cataract condition to one of five categories for surgeon pre-selected	• The imaging system of the LENSAR Laser System finds lens surfaces in order to correctly place pulses into the lens. Upon finding the lens surfaces, the imaging system also determines the location and degree of the nuclear cataract within the lens. The surgeon then has the ability to pick from a variety of fragmentation patterns as the surgeon sees fit. Additionally, the pattern itself can be altered in size and thereby the number of shots as the surgeon sees fit. • LENSAR Laser System provides a mechanism for the doctor to change the size and type of pattern as the surgeon sees fit. For convenience, the System is also provided with an optional mechanism for intra-operatively matching the nuclear cataract condition to one of four categories for surgeon pre-selected	• Not Applicable.

Table 1: Summary of Technological Characteristics			
Characteristics	**Proposed Device** **LLS-fs 3D Laser System 510(k) K182795**	**Predicate Device (Radial Cuts/Incisions)** **LLS-fs 3D Laser System 510(k) K181430 Cleared: 08/09/2018**	**Predicate Device (Tunnels for Corneal Ring Segments) WaveLight FS200 Laser System 510(k) K141476 Cleared: 09/30/2014**
	fragmentation (CustomFrag). • The LENSAR Laser System utilizes surgeon confirmation for planning and positioning of guidance for laser shot placement.	fragmentation (CustomFrag). • The LENSAR Laser System utilizes surgeon confirmation for planning and positioning of guidance for laser shot placement.	
Intended Use for the Capsular IntelliAxis (IntelliCap) Feature	• Using standard pre-operative data, the System places laser marks onto the lens capsule as part of the capsulotomy to identify the astigmatic axis as prescribed by the surgeon.	• Using standard pre-operative data, the System places laser marks onto the lens capsule as part of the capsulotomy to identify the astigmatic axis as prescribed by the surgeon.	• Not Applicable.

* LENSAR estimate only (some WaveLight® parameters were not in the public domain as of this writing and, therefore, LENSAR estimates cannot be confirmed).

The laser parameters that differ slightly from the predicate device (K141476) are Pulse Duration, Repetition Rate, and Maximum Pulse Energy (listed in the table above). The settings for these parameters are based on pre-clinical testing results. Included in this process is the optimization of additional treatment parameters. Clinical safety and effectiveness of tunnels for corneal ring segments are qualified by: a) incision depth accuracy, b) ring tunnel depth regularity, c) ring tunnel incision quality, and whether the incision after the ICRS insertion is acceptable.

7.0 PERFORMANCE DATA

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

Performance Evaluation:

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 indications and other software changes 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 corneal tunnel was tested using a porcine *ex vivo* eye model. The depth of the tunnel was 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 of the corneal tunnel.
- For both the corneal tunnel and radial incisions in combination with arcuate incisions an assessment of the incision quality was conducted. The study consisted of using the laser to cut corneal tunnel and radial incisions (individually or in combination with arcuate incisions) at various depths in porcine eyes. A trained biomedical scientist, using standard instruments, assessed the acceptability for each as it relates to ease of opening and incision quality. The results showed that the proposed device showed ease of opening and quality of incision quality that was acceptable.
- 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.
- The accuracy of the depth of the radial incisions in combination with arcuate incisions was tested using a porcine *ex vivo* eye model. The depth of the radial and arcuate incisions was 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 of the radial incision individually or in combination with the arcuate incision.
- 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 indications and other minor changes meet the performance specifications and requirements. The comparison with the predicate devices 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 corneal tunnels and to the LENSAR Laser System – fs 3D (LLS-fs 3D) for the indication of use in the creation of partial thickness single planed radial incisions.

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:

The Patient Interface Device (PID) Kits have no changes to the material or assembly as part of this submission and thus remains unchanged from that used with the previously cleared device (K181430).

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 (K181430), 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 added indications for use and other minor changes as described in Section 6 above 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 indications 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 (K181430) as it relates to radial cuts and other minor changes; and
- the WaveLight® FS200 Laser System predicate device (K141476) as it relates to tunnels for placement of corneal ring segments.