June 9, 2022

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

Re: K220259
Trade/Device Name: ALLY Adaptive Cataract Treatment System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: April 29, 2022
Received: May 2, 2022

Dear Mr. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Anjana Jain, PhD
Assistant Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220259

Device Name

ALLY™ Adaptive Cataract Treatment System

Indications for Use *(Describe)*

The ALLY™ Adaptive Cataract Treatment System 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.

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.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

This 510(k) Summary has been prepared in accordance with the requirements of 21 CFR 807.92.

1.0 SUBMITTER INFORMATION

Company/Owner: LENSAR, Inc.
2800 Discovery Drive, Suite 100
Orlando, FL 32826
Phone: (407) 641-4889
Fax: (407) 386-7228

Contact Person: Keith Peck
Phone: (888) 575-6412
Fax: (407) 386-7228

Date Summary Prepared: June 8, 2022

2.0 DEVICE INFORMATION

Trade/Proprietary Name: ALLY™ Adaptive Cataract Treatment System

Regulation Number: 21 CFR 886.4390

Regulation Name: Ophthalmic Laser

Regulatory Classification: Class II

Product Code: OOE

Review Panel: Ophthalmic

3.0 LEGALLY MARKETED DEVICES

The legally marketed devices to which LENSAR is claiming equivalence to are:

510(k) Number	Device Name	Manufacturer
K182795	LENSAR Laser System – fs 3D (LLS-fs 3D)	LENSAR, Inc.

4.0 DEVICE DESCRIPTION

The ALLY™ Adaptive Cataract Treatment System (ALLY™ System) is a medical device intended for use in ophthalmic surgery. The ALLY™ System brings the precision of femtosecond laser to the cataract procedure. The ALLY™ System allows for an initial femtosecond laser procedure using a dual-pulse-width laser used to cut a precision capsulotomy in the anterior lens capsule; laser-assisted fragmentation of the cataractous lens for removal during cataract surgery; and 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 ALLY™ System provides automated precision and 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; and the size, architecture, location, depth, and quantity of partial thickness incisions within the cornea.

The ALLY™ System uses Streamline® to integrate pre-op analysis devices, automated iris registration with automatic cyclorotation adjustment, IntelliAxis-C® (corneal), and IntelliAxis Refractive Capsulorhexis® (lens) markers for alignment of toric IOLs, as well as treatment planning tools for precision-guided laser treatments.

5.0 INDICATIONS FOR USE

The ALLY™ Adaptive Cataract Treatment System 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.

6.0 TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The following table provides a comparative between the ALLY™ System and the predicate device.

Summary of Technological Characteristics		
	Subject Device	**Predicate Device**
Characteristic	**ALLY™ Adaptive Cataract Treatment System, 510(k) K220259**	**LLS-fs 3D Laser System 510(k) K182795**
Class / Product Code / Regulation No.	Class II / OOE / 886.4390	Class II / OOE / 886.4390
Intended Type of Use	Prescription Use	Prescription Use
Indications for Use	The ALLY™ Adaptive Cataract Treatment System 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.	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

Summary of Technological Characteristics		
	Subject Device	**Predicate Device**
Characteristic	**ALLY™ Adaptive Cataract Treatment System, 510(k) K220259**	**LLS-fs 3D Laser System 510(k) K182795**
		resection of the cornea to create tunnels for placement of corneal ring segments. • 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
Patient Contact Portion of Device (PID)	Disposable polycarbonate/silicone patient interface accessory; suction ring assembly	Disposable polycarbonate/silicone patient interface accessory; suction ring assembly
Sterilization Method (Accessories)	Ethylene Oxide (EO)	Gamma irradiation (not including Curved Contact PID) or Ethylene Oxide (EO)
Laser Type	Yb:YAG	Yb:YAG
Wavelength	1030 nm	1030 nm
Pulsing	Mode-locked	Mode-locked
Mode	Fundamental (TEM00)	Fundamental (TEM00)
Pulse Duration	320 - 1500 fs	1.5 $x10^{-12}$ sec
Repetition Rate	Variable (320 kHz max)	20-80 kHz, adjustable
Maximum Pulse Energy	15 µJ	15 µJ
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)
Beam Targeting and Delivery	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
Intended Use for Iris Registration Feature	Same as predicate device (K182795).	• 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 the pre-marked eye in the upright position to that of the supine position by way of software reticules, or by the

Summary of Technological Characteristics		
	Subject Device	**Predicate Device**
Characteristic	**ALLY™ Adaptive Cataract Treatment System, 510(k) K220259**	**LLS-fs 3D Laser System 510(k) K182795**
		System's ability to analyze and match iris features between images acquired in each position.
Intended Use for the Cataract Density Imaging Feature	Same as predicate device (K182795).	• The imaging 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 density/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. • The 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 fragmentation (CustomFrag). • The system utilizes surgeon confirmation for planning and positioning of guidance for laser shot placement.
Intended Use for the IntelliAxis Refractive Capsulorhexis® Feature	Same as predicate device (K182795).	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.

7.0 DETERMINATION OF SUBSTANTIAL EQUIVALENCE

7.1 Non-Clinical Performance Data

Design verification and validation testing was completed to demonstrate that the proposed device performance complies with specifications and requirements identified for the ALLY™ Adaptive Cataract Treatment System. 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 ALLY™ Adaptive Cataract Treatment System meets all performance specifications and requirements. The objectives defined in the validation plan were achieved according to the validation results.

The comparison to the predicate device shows that the ALLY™ Adaptive Cataract Treatment System is substantially equivalent. The minor differences between the additional ALLY™ Adaptive Cataract Treatment System device features and the predicate device do not raise any new questions of safety or effectiveness.

7.2 Eye Safety Analysis Testing

A detailed analysis of the retinal and corneal burn hazard analysis for capsulotomy, fragmentation, clear corneal and arcuate incisions under worst-case normal and single failure conditions was performed in accordance with ANSI Z-136.1:2014, with the conclusion that the ALLY™ Adaptive Cataract Treatment System laser is safe with regards to retinal and corneal illumination for the defined indications.

7.3 Biocompatibility Testing

Minor changes to materials used in the ALLY™ System Patient Interface Device (PID) and the addition of the PVC alignment card that is temporarily placed on the patient's head to facilitate system alignment underwent biocompatibility testing per *ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process (3 ed.)*. Test results indicated that the PVC alignment card and the minor materials changes met all biocompatibility requirements.

7.4 Sterilization Validation

There have been no changes to the ALLY™ System PID or PID Ring Arm as detailed and previously cleared with the LLS-fs 3D (K182795) to the sterilization provider, sterilization methodology, profile/chamber, or sterility assurance level.

The ALLY™ System includes a sterile drapes kit (used for monitors, handles, joystick, tray; and an alignment card). This drapes kit has the same packaging as the drapes kit previously cleared for the predicate device in K182795. The drapes for the ALLY™ System have been updated and were adopted into the family of products already validated.

7.5 Sterile Device Packaging

Packaging for the sterile Patient Interface Device (PID) and Drapes Kit has been performed. Test results satisfied the acceptance criteria as defined by the recognized standards (ISTA 3A, ASTM F2096, ASTM F88) and found to be in compliance with the recognized standards.

7.6 Electromagnetic Compatibility and Electrical Safety

The ALLY™ Adaptive Cataract Treatment System has undergone electromagnetic compatibility and electrical safety testing to support this premarket notification. Test results satisfied the acceptance criteria as defined by the recognized standards (ANSI/AAMI/IEC 60601-1-2:2014, ANSI/AAMI/ES 60601-1:2005 A1:2012) and found to be in compliance with the applicable recognized safety standards.

7.7 Hazard Analysis

A hazard analysis was conducted to identify all potential hazards to the patient, surgeon, and other system operators resulting from differences between the ALLY™ Adaptive Cataract Treatment System and the predicate device, LLS-fs 3D (K182795). The identified hazards were duly evaluated in the risk analysis, and mitigation measures were defined and tested. After the implementation and testing of mitigation measures, the benefit of the ALLY™ Adaptive Cataract Treatment System prevails over the residual risks and all potential hazards have acceptable levels of probability/severity characteristics.

7.8 Software Verification and Validation Testing

A complete software verification and validation testing of the ALLY™ Adaptive Cataract Treatment System was conducted. The results demonstrate that the ALLY™ Adaptive Cataract Treatment System is in compliance with the following recognized standard: IEC 62304. Documentation was provided as recommended in *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices: Guidance for Industry and FDA Staff (May 11, 2005)*. 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.

7.9 Animal Studies Performance Data

No animal studies were performed to support substantial equivalence of this premarket notification.

7.10 Clinical Performance Data

No clinical studies were deemed necessary to demonstrate the safety and effectiveness or substantial equivalence of the ALLY™ Adaptive Cataract Treatment System to the predicate device. The non-clinical performance data demonstrated that the device performs as intended.

8.0 CONCLUSIONS FROM NON-CLINICAL AND CLINICAL DATA

The ALLY™ Adaptive Cataract Treatment System has the same intended use, indications for use, and similar design and fundamental and scientific technology as the predicate device. The non-clinical performance data demonstrate that the ALLY™ Adaptive Cataract Treatment System is substantially equivalent to the predicate device and does not raise any new issues of safety or effectiveness. Thus, the ALLY™ Adaptive Cataract Treatment System is substantially equivalent to the predicate device.