May 18, 2020

AMO Manufacturing USA, LLC
Laarni Ricafort
Project Manager, Regulatory Affairs
510 Cottonwood Drive
Milpitas, CA 95035

Re: K200056
Trade/Device Name: Catalys Precision Laser System
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic Laser
Regulatory Class: Class II
Product Code: OOE
Dated: April 16, 2020
Received: April 20, 2020

Dear Laarni Ricafort:

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,

for Tieuvi Nguyen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200056

Device Name
CATALYS® Precision Laser System

Indications for Use *(Describe)*
The CATALYS® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of 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

[807.92(a)(1)] Submitter Information

Sponsor/Submitter: AMO Manufacturing USA, LLC
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Contact Person: Laarni Ricafort
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Date Summary Prepared: May 7, 2020

[807.92(a)(2)] Name of Device

Device Trade Name: CATALYS® Precision Laser System

Common Name: Ophthalmic laser

Device Classification: Class II

Regulation Number: 21 CFR 886.4390

Classification Name: Ophthalmic Femtosecond Laser

Product Code: OOE

[807.92(a)(3)] Legally Marketed Devices

Primary Predicate Device: CATALYS® Precision Laser System
(K182083, November 9, 2018)

Reference Predicate Device LENSAR Laser System (LLS-fs 3D)
(K182795, December 21, 2018)

[807.92(a)(4)] Device Description

Device Description:

Catalys® Precision Laser System ophthalmic surgical laser system used in healthcare facilities such as hospitals, Ambulatory Surgery Centers (ASCs) and surgeon office settings. The System is an electromedical device that contains software. System components include a single-use Liquid Optics™ Interface and optional Mobile Patient Bed.

The Catalys® Precision Laser System (also referred to as the Catalys® System or System) is an ophthalmic surgical laser system indicated for use in cataract surgery to create a precise anterior capsulotomy and/or to effect lens fragmentation, thus facilitating efficient lens removal. The System also creates 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 System employs femtosecond ("FS") laser technology with integrated Optical Coherence Tomography ("OCT"), all of which are controlled and monitored by dedicated electronics. The System utilizes a common optical path for the OCT and femtosecond treatment laser (including the three-dimensional scanner and Liquid Optics™ [patient] Interface). As such, the beams are intrinsically co-registered and provide for precise overlap between imaging and treatment beams. Ocular surfaces recognized by the system software include anatomy within the anterior chamber, such as the anterior and posterior corneal surfaces and the anterior and posterior surfaces of the crystalline lens. Detailed axial or sagittal cross-sectional views are available via OCT, to demarcate proposed incisions versus adjacent ocular structures (for example, iris, pupil and limbus).

The Catalys® Precision Laser System laser classification per 21 CFR 1040.10 and 1040.11 is Class 4.

[807.92(a)(5)] Intended Use

Indications for Use:

The Catalys® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of 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.

Difference in Indications from

The Catalys® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens.

Primary Predicate Device	Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of 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 subject device and primary predicate device have the same indications for use.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:

The modified Catalys Precision Laser System is unchanged with regard to its technological characteristics, indications for use, and intended uses. The software revisions in the modified device include updates to the graphical user interface and host to improve the efficiency of the workflow as well as the addition of software modules to support the import of patient exams and iris registration. The revisions in the modified device are constrained to only software changes, of which most are related to advanced astigmatism management and additional improvements to currently implemented features.

Software verification and validation testing in addition to bench testing was performed to verify the ability of the software to meet its intended use and to ensure that no adverse effects were introduced due to the software changes. This testing included subsystem level verification and regression testing as well as system validation using the latest software, Mobile Patient Bed, and Liquid Optics Interface.

The following table provides a comparison of the primary predicate device, reference predicate device, and subject device for the purpose of demonstrating substantial equivalence to the predicate devices for its indication for use, intended use, technological characteristics and added new features.

Similarities and Differences Between Cleared Predicate Devices and Subject Device

Attribute	Subject Device Catalys Precision Laser System	Primary Predicate Device Catalys Precision Laser System	Reference Predicate Device LENSAR Laser System LLS-fs 3D Laser System
510(k) Number	K200056	K182083	K182795
Regulation Number	886.4390	886.4390	886.4390
Regulation Name	Ophthalmic Laser	Ophthalmic Laser	Ophthalmic Laser
Regulatory Class	Class II	Class II	Class II
Product Code	OOE	OOE	OOE
Indications for Use	The Catalys® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of 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 Catalys® Precision Laser System is indicated for use in patients undergoing cataract surgery for removal of the crystalline lens. Intended uses in cataract surgery include anterior capsulotomy, phacofragmentation, and the creation of 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 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 multiplane 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;
System Type	Opthalmic Femtosecond Laser with Spectral Domain OCT	Opthalmic Femtosecond Laser with Spectral Domain OCT	Not applicable
Laser Mechanism of Action	Plasma, Cavitation	Plasma, Cavitation	Not applicable
Treatment Laser Wavelength (nm)	1030 ±5	1030 ±5	Not applicable
Output Power, Max	Per ISO 15004-2:2007 limits	Per ISO 15004-2:2007 limits	Not applicable
Maximum Pulse Energy (µJ)	10	10	Not applicable
Repetition Rate (kHz)	9-120	9-120	Not applicable

Attribute	Subject Device Catalys Precision Laser System	Primary Predicate Device Catalys Precision Laser System	Reference Predicate Device LENSAR Laser System LLS-fs 3D Laser System
Pulse Duration (fs)	< 600	< 600	Not applicable
Spot Size; diameter (µm)	5	5	Not applicable
System controls	Microprocessor with Graphical User Interface	Microprocessor with Graphical User Interface	Not applicable
Patient Contact Interface	Suction-ring type interface devices (marketed as Liquid Optics™ Interface) Sterile and Single-use Cleared on K141079 & K170322	Suction-ring type interface devices (marketed as Liquid Optics™ Interface) Sterile and Single-use Cleared on K141079 & K170322	Not applicable
LOI Suction Ring Seal Diameters (mm)	LOI External (mm): 21.6 Internal (mm): 14.1 LOI-12 External (mm):19 Internal (mm):12	LOI External (mm): 21.6 Internal (mm): 14.1 LOI-12 External (mm):19 Internal (mm):12	Not applicable
	0180-1401 External (mm): 21.6 Internal (mm): 14.1 0180-1201 External (mm): 19 Internal (mm): 12	0180-1401 External (mm): 21.6 Internal (mm): 14.1 0180-1201 External (mm): 19 Internal (mm): 12	Not applicable
OCT Axial Resolution (µm)	30	30	Not applicable
OCT transverse Resolution (µm)	15	15	Not applicable
Scan speed (A-scans/sec)	1000	1000	Not applicable
A-scan depth (nm)	2	2	Not applicable
Optical Source	820-930	820-930	Not applicable
Optical Power	ANSI Class 1 < 3.48mW at cornea	ANSI Class 1 < 3.48mW at cornea	Not applicable
Iris Imaging	Live iris view	Live iris view	Not applicable
Trajectory Timing Synchronization	FPGA coordinates from one non--reentrant VI	FPGA coordinates from one non--reentrant VI	Not applicable
Communication Method for Watchdog for Host PC with the Mobile Patient Bed Pairing	Direct FPGA Interface	Direct FPGA Interface	Not applicable
Software Features	Built-in Nomogram: Inclusion of nomogram formula calculator for arcuate incisions	The items listed under the "subject device" column are new features. All other software features not	Not applicable

Attribute	Subject Device Catalys Precision Laser System	Primary Predicate Device Catalys Precision Laser System	Reference Predicate Device LENSAR Laser System LLS-fs 3D Laser System
	Toric Alignment Marks: New geometry of intrastromal corneal incisions in a radial line	listed remain unchanged from the primary predicate device	Not applicable
	Lens Fragmentation Alignment: Ability to rotate the orientation of the fragmentation pattern to deliver into cataractous lens		Not applicable
	Pre-op Manual Entry: New data fields to allow the operator to input patient corneal measurements related to astigmatism		Not applicable
	Pre-op Import: Ability to import patient corneal measurements and eye image from a Cassini corneal topographer via encrypted data transfer	Not applicable	Pre-op Import: Integration with pre-op analysis devices.
	Iris Registration: Account for cyclorotation between upright and supine position using imported eye image	Not applicable	Iris Registration: Automated iris registration with automatic cyclorotation adjustment

[807.92(b)(1)] Determination of Substantial Equivalence

Non-Clinical Performance Data:

The 6.0 software within the subject device was subjected to hardware and software bench tests, in conjunction with simulated use testing.

Software-specific bench testing of the Catalys® System was conducted to demonstrate the System's ability to meet all intended design specifications related to the software design changes.

Bench testing of the primary predicate device is directly applicable to the subject device as there are no significant changes to the subject device other than the design changes resident in the software. The modified device employs additional tests to verify the performance of the laser's ability to execute the intended trajectory.

	Bench testing, when coupled with software regression testing, verification and validation testing presented for the subject device, including regression testing provides reasonable assurance that the System remains safe and effective for its intended use and furthermore, that it is substantially equivalent to the identified primary predicate device
Clinical Performance Data:	Clinical Data was deemed not necessary for the Catalys® Precision Laser System. The performance data demonstrated that the device performs as intended. The proposed device does not include any changes to the indications for use or intended use of the primary predicate device. It does not introduce any new harms or unacceptable risks, and therefore does not require clinical testing to assess safety and performance or to demonstrate equivalence.

[807.92(b)(3)] Conclusion

Conclusions from Non-Clinical and Clinical Tests:	The modified Catalys Precision Laser System is substantially equivalent to the currently cleared Catalys Precision Laser System. The changes in software between the primary predicate and the modified device do not raise new questions of safety and efficacy of the new device. The Catalys Precision Laser System is substantially equivalent to the primary predicate in terms of indications for use, technological characteristics and fundamental scientific technology. The mechanism of laser cutting is the same for both systems, in that the ultra-short laser pulses create a highly localized plasma and subsequent cavitation event that, when controlled by a computerized scanning system, direct the laser beam through a three-dimensional pattern to produce a precise capsulotomy, fragment the crystalline lens and create arc cuts/incisions in the cornea.