May 17, 2022

AMO Manufacturing USA, LLC
Alex Etlin
Senior Specialist, Regulatory Affairs
510 Cottonwood Drive
Milpitas, California 95035

Re: K220516
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: February 23, 2022
Received: February 25, 2022

Dear Alex Etlin:

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)*
K220516

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

The following 510(k) Summary is being submitted in accordance with the requirements of 21 CFR 807.92

[807.92(a)(1)] Submitter Information

Sponsor/Submitter: AMO Manufacturing USA, LLC
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Date Summary Prepared: May 13, 2022

[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	
Predicate Device:	CATALYS® Precision Laser System (K210701, cleared on April 7, 2021)
Reference Device	CATALYS® Precision Laser System (K170322, cleared on May 19, 2017)

[807.92(a)(4)] Device Description

Device Description:

Catalys® Precision Laser System is an ophthalmic surgical laser system used in healthcare facilities such as hospitals, Ambulatory Surgery Centers (ASCs) and surgeon office settings. The Catalys® Precision Laser System is an electromedical device which 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 21 CFR 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 Predicate Device:

The subject device and the predicate device have the same indications for use.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics:	The modified System is unchanged in regard to its technological characteristics, indications for use, and intended uses. The scope of change for this submission is constrained to only the sterile, single-use patient-user interface (known as Liquid Optics Interface or LOI) that will be manufactured by an alternate third-party-manufacturer (TPM) Flextronics Medical (Tijuana, Mexico also known as Flex). The project name given to establishing Flex as an alternate manufacturer is Gen3 LOI, and therefore hereon the subject device will be referred to as Gen3 LOI (it does not indicate a new version of the device). The Gen2 LOI manufactured by current TPM, Juno Pacific (Soquel, CA, USA), remains unchanged. The only modifications made to Gen3 LOI are: 1) a minor modification of sterilization cycle parameters (without change of modality or the sterility assurance level), 2) the use of alternate colorant in the Suction Seal Ring sub assembly and 3) removal of unnecessary feature in the form of tabs originally intended to hold the lens cone when not in use. These changes are minor and are intended to improve manufacturing capacity and reduce production costs. These changes do not introduce new risks, do not impact the safety, efficacy, nor substantial equivalence of the device. Bench testing was performed to confirm the ability of the Gen3 LOI to meet the intended use with the System and to ensure that no new risks or adverse effects have been introduced, due to the proposed changes. Testing included sterilization cycle validation, sub-system level verification as well as system validation, shelf-life and biocompatibility testing.

Substantial Equivalence Summary

Characteristic	Predicate Device	Subject Device
510(K) Number	K210701, cleared April 07, 2021 (predicate) K170322, cleared May 19, 2017 (reference)	This submission
21 CFR Number	886.4390	Same
Regulation Name	Ophthalmic Laser	Same
Regulatory Class	Class II	Same
Product Code	OOE	Same
Indication 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.	Same
System Type	Ophthalmic Femtosecond Laser with Spectral Domain OCT	Same
Laser Mechanism of Action	Plasma, Cavitation	Same
Laser Beam Positioning	Computer-controlled 3-dimensional scanning system	Same
Treatment Laser Wavelength (nm)	1030±5	Same
Output Power, Max	per ISO 15004-2:2007 limits	Same
Maximum Pulse Energy (μJ)	10	Same
Repetition Rate (kHz)	9–120	Same
Pulse Duration (fs)	< 600	Same
Spot Size; diameter (μm)	5.0	Same
System Controls	Microprocessor with Graphical User Interface	Same
Patient Contact Interface	Suction ring-type interface (Liquid Optics Interface); sterile and single-use	Same
LOI Suction Ring Seal Diameters (mm)	0180-1401 External (mm): 21.6 Internal (mm): 14.1 0180-1201 External (mm): 19	Same

Characteristic	Predicate Device	Subject Device
	Internal (mm): 12	
OCT axial resolution (μm)	30	Same
OCT transverse resolution (μm)	15	Same
Scan speed (A-scans/sec)	1000	Same
A-scan depth (mm)	2	Same
Optical source	820 – 930	Same
Optical power	ANSI Class 1 < 3.48 mW at cornea	Same
Iris Imaging	Live iris view	Same
Trajectory Timing Synchronization	FPGA coordinates from one non--reentrant VI	Same
Communication Method for Watchdog for Host PC with the Mobile Patient Bed Pairing	Direct FPGA Interface	Same
Software Features	Built-in Nomogram Toric Alignment Marks Lens Fragmentation Alignment Pre-op Manual Entry Pre-op Import Iris Registration	Same

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

Non-Clinical Performance Data:

Bench testing of the System (K210701, cleared on April 7, 2021) in regard to the delivering a variety of laser patterns intended for capsulotomy, phacofragmentation and corneal incisions with corresponding accuracy and precision is directly applicable to the subject device since there are no changes to the Catalys System's hardware nor software.

Also, all bench testing, previously performed for the Gen2 Liquid Optic interface manufactured by Juno Pacific, Soquel, CA (reference device resident in K170322, cleared May 19, 2017) is directly applicable and unchanged. All testing subject to this submission is limited to the Gen3 LOI.

Sterilization cycle validation for the Gen3 LOI was carried out using the conservative overkill approach and as defined by *ISO 11135* and *AAMI TIR28* (as applicable). Like the sterilization cycle of the reference device, the subject

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

sterilization cycle utilizes a 100% Ethylene Oxide (EO) sterilization modality resulting in a minimum 10^{-6} SAL. All acceptance criteria were met.

Performance testing conducted for the Gen3 LOI has been carried out according to the same principles and included the same tests as for the reference Gen2 LOI. Tests were performed at baseline time point T=0 (before aging) and at T=24 (after accelerated aging equivalent to 24 months). The acceptance criteria remain unchanged between Gen2 and Gen3 LOI. All acceptance criteria have been met.

Biocompatibility testing was performed to demonstrate that the colorant used in the processing of the Suction Seal Ring sub assembly of the Gen3 LOI is biocompatible for the finished sterile product configuration. Testing confirmed no leaching and no cytotoxicity for this minor colorant addition.

Bench testing presented for the subject device provides reasonable assurance that the System with the LOI remains safe and effective for its intended use and furthermore, that it is substantially equivalent to the identified reference device.

Clinical Performance Data:

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.
The performance data demonstrated that the device performs as intended.

[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 the LOI do not raise new questions of safety and efficacy of the device. The Catalys Precision Laser System is substantially equivalent to the 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.