November 9, 2018

AMO Manufacturing USA, LLC
James Garvey II
Associate Director, Regulatory Affairs
510 Cottonwood Drive
Milpitas, CA 95035

Re: K182083
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: August 29, 2018
Received: August 30, 2018

Dear James Garvey II:

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 yours,

Bradley S. Cunningham -A

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

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)*
K182083

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[807.92(a)(1)] Submitter Information	
Sponsor/Submitter:	AMO Manufacturing USA, LLC 510 Cottonwood Drive Milpitas, CA 95035, USA Phone: 408-723-5166 Fax: 408-273-5966
Contact Person:	Patrick Garvey Associate Director, Regulatory Affairs Email: pgarvey@its.jnj.com Phone: 408-723-5166 Fax: 408-273-5966
Date Summary Prepared	October 29, 2018
[807.92(a)(2)] Name of Device	
Device Trade Name:	Catalys® Precision Laser System[1]
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 (K172002, August 25, 2017)
[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 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

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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] Interface1). 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).

In addition to the laser classifications per 21 CFR 1040.10 and 1040.11, the Catalys® Precision Laser System complies with the requirements for Class I lasers per ANSI Z136.1-2007.

[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	There are no differences in the Indications for Use from the predicate device. Table 1 of this summary provides a summary of the changes from the predicate device.

[807.92(a)(6)] Technical Characteristics

Technological Characteristics	The modified Catalys® Precision Laser System is unchanged in regards to its technological characteristics, indications for use, and intended uses. The software revisions in the modified device include updates to hardware communication timing to reduce false positive alarms, graphical user interface changes to support use of the Mobile Patient Bed in environments with multiple Catalys systems, and a revision associated with trajectory timing offsets seen most evidently in the alignment verification function of the System. 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 have been introduced due to the software change. 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

A substantial equivalence summary is provided in the **Table 1** immediately below:

Table 1: Substantial Equivalence Summary

Attribute	Predicate Device	Subject Device
510(k) Number	K172002	TBD
Regulation Number	886.4390	Same
Regulation Name	Ophthalmic Laser	Same
Regulatory Class	Class II	Same
Product Code	OOE	Same
Indications for Use	The OptiMedica® 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	Same

(continued next page)

Table 1: Substantial Equivalence Summary – continued.

System controls	Microprocessor with Graphical User Interface		Same
Patient Contact Interface	Suction ring-type interface devices (marketed as Liquid Optics™ Interface) Sterile and Single-use Cleared on K141079 & K170322		Same
LOI Suction Ring Seal Diameters (mm)	**LOI** External (mm): 21.6 Internal (mm): 14.5	**LOI-12** External (mm): 19 Internal (mm): 12	Same
	0180-1401 External (mm): 21.6 Internal (mm): 14.5	**0180-1201** External (mm): 19 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 < 3.48mW at cornea		Same
Iris Imaging	Live iris view		Same
Trajectory Timing Synchronization	FPGA coordinates from one of two copies of the reentrant VI		FPGA coordinates from one non--reentrant VI
Communication Method for Watchdog for Host PC with the Mobile Patient Bed Pairing	USB Interface		Direct FPGA Interface
Software Features	Changes to provide compatibility with Generation 2 Liquid Optics Interface and Mobile Patient Bed		• Watchdog improvements to reduce potential for false alarms • Improved handling of multiple MPBs in use environment • Changes to address a cut trajectory shift issue

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

Non-Clinical Performance Data

The 5.00.33 and 5.00.34 software configurations of the subject device we 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 predicate device (resident in K172002) with regards to the ability to deliver a variety of laser patterns intended for capsulotomy,

	phacofragmentation and corneal incisions with corresponding accuracy and precision 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 predicate device.
Clinical Performance Data	Clinical data was not necessary for the Catalys® Precision Laser System. The performance data demonstrated that the device performs as intended.
[807.92(b) (3)] Conclusion	
Conclusion 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 predicate device and modified device do not raise new questions of safety and efficacy of the modified device. The Catalys® Precision Laser System is substantially equivalent to the predicate device (as cleared via K172002) 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.