DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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August 25, 2017

AMO Manufacturing USA, LLC
Anita Xavier
Senior Specialist, Regulatory Affairs
510 Cottonwood Drive
Milpitas, CA 95035

Re: K172002
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: July 5, 2017
Received: July 6, 2017

Dear Anita Xavier:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education (DICE) at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Denise L. Hampton -S

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

Indications for Use

510(k) Number: K172002

Device Name: Catalys Precision Laser System

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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

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

Applicant

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Contact Person

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Date Prepared

29 June 2017

Classification

Class II
Regulation Number: 21 CFR 886.4390
Regulation Name: Ophthalmic laser
Classification Product Code: OOE
Classification Product Code Name: Ophthalmic Femtosecond Laser

Trade Name

Catalys Precision Laser System

Predicate Devices

Catalys Precision Laser System; K170322, cleared 19 May 2017

Intended Use

The ***OptiMedica Catalys*** [1]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.

[1] CATALYS®, OPTIMEDICA, LIQUID OPTICS and INTEGRAL GUIDANCE are trademarks owned by or licensed to Abbott Laboratories, its subsidiaries or affiliates.

Device Description

The Catalys Precision Laser System ("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*** [2][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).

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 4 lasers per ANSI Z136.1-2007.

Substantial Equivalence

The Catalys Precision Laser System is substantially equivalent to the predicate device (as cleared via K170322) 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.

As compared to the predicate device, the subject device has an upgraded software version cOS 5.0 and the Mobile Patient Bed which serves the same purpose as the current Patient Chair with the Catalys Precision Laser System. The upgraded Catalys System software cOS 5.0 is intended to provide compatibility of the Mobile Patient Bed with the Catalys Precision Laser System. The software version cOS 5.0 has also been tested to ensure backward compatibility with the current Patient Chair. The Catalys System with the upgraded software version cOS 5.0 will also continue to provide compatibility of the Liquid Optics Interface and Generation 2 Liquid Optics Interface which was most recently cleared under K170322.

[2] CATALYS®, OPTIMEDICA, LIQUID OPTICS and INTEGRAL GUIDANCE are trademarks owned by or licensed to Abbott Laboratories, its subsidiaries or affiliates.

Summary of Bench and Animal Performance Testing

Bench testing related to the performance of the Catalys Precision Laser System with the upgraded software and the use of the Mobile Patient Bed with the Catalys System was conducted to demonstrate the System's ability to meet all intended design specifications related to the subject device changes. The following testing was performed to verify the requirements related to the subject device design changes:

- Software specific bench testing of the Catalys System and the Mobile Patient Bed was conducted to ensure the use of Mobile Patient Bed with the Catalys Precision Laser System and the overall Catalys System's ability to continue to perform as intended.
- Hardware specific bench testing of the Mobile Patient Bed was conducted to verify the mechanical hardware requirements and to ensure that the Mobile Patient Bed functions as a stable patient support system
- Electrical safety and EMC testing specific to the use of Mobile Patient Bed and its communication with the Catalys Precision Laser System was conducted by Intertek testing Laboratories to ensure compliance to the electrical safety standards
- Biocompatibility testing was performed to ensure that the Mobile Patient Bed upholstery meets requirements of ISO 10993-1
- Design validation was performed to validate the subject device requirements and it's functionality with the Catalys System with cOS 5.0 software

Overall, bench testing demonstrated that subject device with cOS 5.0 continues to deliver incisions as intended. Bench testing of the predicate device 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 software change and the use of the Mobile Patient Bed with the Catalys Precision Laser System.

The bench testing provided in K170322, when coupled with the verification and validation testing presented for the subject device, provides reasonable assurance that the System is safe and effective for its intended use and furthermore, that it is substantially equivalent to the identified predicate device.