DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 19, 2015

Abbott Medical Optics, Inc.
% Ms. Christine Chun
Senior Regulatory Affairs Specialist
1700 East St. Andrew Place
Santa Ana, CA 92705

Re: K151636
Trade/Device Name: Amo Whitestar Signature Pro Phacoemulsification System, Whitestar Signature Pro Advance Linear (four-button) Foot Pedal, Whitestar Signature Pro (wireless) Remote Control
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: September 11, 2015
Received: September 14, 2015

Dear Christine Chun:

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 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 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 yours,

Eric A. Mann -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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
Unknown at this time

Device Name

AMO WHITESTAR Signature Pro Phacoemulsification System

Indications for Use *(Describe)*

The AMO WHITESTAR Signature Pro Phacoemulsification System is a modular ophthalmic microsurgical system that facilitates anterior segment (i.e., cataract) ophthalmic surgery. The modular design allows the users to configure the system to meet their surgical requirements.

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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6 510(k) SUMMARY

6.1 APPLICANT INFORMATION

This 510(k) summary is being submitted in accordance with the Medical Device Amendments of 1976, the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92.

Submitter Information:	Abbott Medical Optics Inc. 1700 E. St. Andrew Place Santa Ana, CA 92705, USA
Contact Person:	Christine Chun Senior Regulatory Affairs Specialist Tel: (714) 247-8487 Fax: (714) 566-3785 email: christine.chun@abbott.com
Date the summary was prepared:	June 12, 2015
Subject device:	Trade/Proprietary Name: AMO WHITESTAR SIGNATURE PRO Phacoemulsification System Common/Usual Name: Cataract Extraction System Classification Name: Phacofragmentation system (21 CFR 886.4670, Product Code HQC)

6.2 SUBSTANTIAL EQUIVALENCE SUMMARY

The AMO WHITESTAR SIGNATURE PRO Phacoemulsification System (“subject device”) is an updated version of its primary predicate device, the legally marketed AMO WHITESTAR Signature Phacoemulsification System cleared in K111697 on September 27, 2011. Like its primary predicate device, the subject device is designed for use by ophthalmologists in the surgical setting to emulsify and remove a cataractous lens from the eye.

The system consists of a console that powers and operates the device, a wireless remote control, and a foot pedal. It is designed to work with phacoemulsification handpieces for phacoemulsification, irrigation/aspiration, vitrectomy, and diathermy, and modular disposable tubing packs, which include fluid aspiration drainage bags, and other foot pedals. The handpieces, packs, and other foot pedals used with the subject device are the same as

those used with the primary predicate device and have been cleared in previous 510(k) filings, and are not within the scope of this premarket notification.

Abbott Medical Optics Inc. (AMO) hereby claims substantial equivalence between the AMO WHITESTAR SIGNATURE PRO Phacoemulsification System console, remote control, and its system components with those contained in the legally-marketed AMO WHITESTAR Signature Phacoemulsification System, cleared in K111697 with the exception of an additional foot pedal accessory. The Advanced Linear Foot Pedal (ALP) used with the subject device is substantially equivalent to the foot pedal used with the legally marketed COMPACT INTUITIV system, cleared in K133115.

Legally marketed devices to which the submitter claims equivalence:

510(k) Number	Clearance Date	Device	Manufacturer
AMO WHITESTAR SIGNATURE PRO Phacoemulsification System - Console			
K111697	09/27/2011	AMO WHITESTAR Signature Phacoemulsification System ***Primary** Predicate Device*	Abbott Medical Optics Inc.
AMO WHITESTAR SIGNATURE PRO Phacoemulsification System – Wireless Remote Control			
K111697	09/27/2011	Remote control cleared with the AMO WHITESTAR Signature Phacoemulsification System ***Primary** Predicate Device* *An accessory to the AMO WHITESTAR Signature Phacoemulsification System*	Abbott Medical Optics Inc.
AMO WHITESTAR SIGNATURE PRO Phacoemulsification System – Advanced Linear Foot Pedal			
K133115	2/27/2014	Foot Pedal cleared with the COMPACT INTUITIV System ***Secondary** Predicate Device* *An accessory to the COMPACT INTUITIV System*	Abbott Medical Optics Inc.

6.3 DEVICE DESCRIPTION SUMMARY

The subject device is the AMO WHITESTAR SIGNATURE PRO Phacoemulsification System, which is an upgrade to the primary predicate device, the AMO WHITESTAR Signature Phacoemulsification System (K111697), **Key device components included in this 510(k) submission are the system console, advanced linear (four-button) foot pedal (ALP), and wireless remote control.** The system console and wireless remote control of the subject device are substantially equivalent to the console and wireless remote control of the primary predicate device in K111697. The Advanced Linear foot pedal (ALP) used with the subject device is substantially equivalent to the foot pedal used with the secondary predicate device, the COMPACT INTUITIV System, cleared under K133115.

The subject device is classified under 21 CFR 886.4670 as a "phacofragmentation system," described as an AC-powered device with a fragmenting needle intended for use in cataract surgery to disrupt a cataract with ultrasound and extract the cataract. Like the primary predicate device in K111697, the subject device is used to perform phacoemulsification by applying ultrasonic energy combined with the mechanical action of a vibrating phaco handpiece to the cataractous lens of the eye. The system performs four basic functions: phacofragmentation, irrigation/aspiration of fluid, diathermy (bipolar), and vitrectomy. The functionality, performance, intended use, and fundamental scientific technology of the AMO WHITESTAR SIGNATURE PRO Phacoemulsification System and its accessories are equivalent to the AMO WHITESTAR Signature Phacoemulsification System cleared in K11169. The functionality, performance, intended use, and fundamental scientific technology of the Advanced Linear Foot Pedal (APL) used with the subject device is equivalent to the foot pedal used with the legally marketed COMPACT INTUITIV system, cleared in K133115.

The intended use of the subject device is anterior segment ophthalmic surgery (cataract), which is the same as the primary predicate device. The materials, energy source, operating mechanism, fundamental scientific technology, physical properties, duration and type of contact, and intended use of the subject device are identical to those of AMO WHITESTAR Signature Phacoemulsification System's console and remote control in K111697, and the COMPACT INTUITIV System's foot pedal in K133115 for the subject device's Advanced Linear foot pedal (APL). The FDA-recognized standards used for performance testing of the subject device are equivalent to those used for the primary predicate device in K111697.

6.4 INDICATIONS FOR USE

The AMO WHITESTAR SIGNATURE PRO Phacoemulsification System is a modular ophthalmic microsurgical system that facilitates anterior segment (cataract) surgery. The modular design allows the users to configure the system to meet their surgical requirements.

6.5 TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE

The main technological characteristics of the AMO WHITESTAR SIGNATURE PRO Phacoemulsification System include phacoemulsification, diathermy, irrigation and aspiration, and vitrectomy. These technological characteristics are the same as those in the legally marketed device, the AMO WHITESTAR Signature Phacoemulsification System (K111697).

- The **Phacoemulsification** mode is used to break up (emulsify) the nucleus of a lens, allowing it to be aspirated from the eye through a small incision.

- The **Diathermy** (bipolar) mode is used to coagulate blood vessels during a surgical procedure and, in some cases, to coagulate the conjunctiva following a procedure.

- The **Irrigation/Aspiration** mode allows for controlled aspiration of cortical material from the eye, while maintaining intraocular stability by replacing aspirated material with a balanced salt solution. A peristaltic pump provides a predictable and stable aspiration rate. Irrigation is gravity-fed, and intraocular pressure can be regulated by adjusting the height of the balanced salt solution bottle.

- The **Vitrectomy** mode is used to cut and remove vitreous from the anterior segment of the eye during secondary intraocular lens implantation, following vitreous loss associated with trauma, or during primary cataract surgery.

These surgery modes are equivalent to the surgery modes of the primary predicate device, the AMO WHITESTAR Signature Phacoemulsification System.

Aside from the technological characteristics, the AMO WHITESTAR SIGNATURE PRO Phacoemulsification System is equivalent to its primary predicate device, the AMO WHITESTAR Signature Phacoemulsification System (K111697), and the Advanced Control Pedal (ALP) of the subject device is equivalent to the secondary predicate device, the foot pedal used in the COMPACT INTUITIV System (K133115), in terms of intended use, design, material, basic scientific concepts, energy source, manufacturing process, and FDA-recognized standards used for performance testing. The intended use of the subject device is anterior segment ophthalmic surgery, which is the same intended use as the primary predicate device.

6.6 SUMMARY OF NON-CLINICAL TESTS

The AMO WHITESTAR SIGNATURE PRO Phacoemulsification System has undergone preliminary design verification and validation to address regulatory requirements, including electromechanical safety testing (IEC testing), and is in compliance with the applicable requirements of safety standards. The subject device passed the acceptance criteria and was found to perform as safely and effectively as the primary predicate device during the following modes of anterior segment ophthalmic surgery: phacoemulsification, irrigation/aspiration, diathermy, and vitrectomy. Therefore, the subject device, including the console, ALP and wireless remote control, has similar safety, effectiveness, and performance profiles as the primary and secondary predicate devices in K111697 and K133115.

The AMO WHITESTAR SIGNATURE PRO Phacoemulsification System was developed and tested in accordance with AMO requirements and specifications, which comply with the following FDA-recognized consensus standards:

ANSI/AAMI/ES 60601-1: 2005	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance. Amendment 1/Amendment 2
EN/IEC 60601-1-2: 2007	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance —Collateral Standard: Electromagnetic Compatibility – Requirements and Tests.
EN/IEC 60601-2-2: 2009	Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High-Frequency Surgical Equipment and High-Frequency Surgical Accessories.
IEC 62304: 2006	Medical Device Software – Software Life Cycle Processes.
IEC 62366: 2007	Medical Device – Application of Usability Engineering to Medical Devices
ISO 14971: 2007	Application of Risk Management to Medical Devices

All materials coming into contact with the patient or the patient fluid path are the same as those in the primary predicate device, have been cleared in previous 510(k) filings, and are outside the scope of this premarket notification.

6.7 SUMMARY OF CLINICAL TESTS

No clinical studies were deemed necessary to determine the safety and effectiveness of the AMO WHITESTAR SIGNATURE PRO Phacoemulsification System.

6.8 CONCLUSION

The technological characteristics that determine the functionality and performance of the subject device, the AMO WHITESTAR SIGNATURE PRO Phacoemulsification System, are substantially equivalent to those cleared under K111697 for anterior segment ophthalmic surgery. The technological characteristics that determine the functionality and performance of the Advanced Linear foot pedal designed for use with the subject device is substantially equivalent to the foot pedal cleared under K133115. The AMO WHITESTAR SIGNATURE PRO Phacoemulsification System will be manufactured in compliance with FDA and ISO quality system requirements. Preliminary system validation and verification data demonstrated that the functional requirements and system specifications were met prior to commercial release.