



April 27, 2016

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

Abbott Medical Optics Inc.
Ms. Priya Viswanathan
Senior Regulatory Affairs Specialist
1700 East Saint Andrew Place
Santa Ana, California 92705

Re: K160236
Trade/Device Name: Dual Pump Pack
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: March 23, 2016
Received: March 25, 2016

Dear Ms. Viswanathan:

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,

 Kesia Alexander

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

Indications for Use

510(k) Number (if known)

K160236

Device Name

DUAL PUMP Pack, Model OPO73

Indications for Use (Describe)

The DUAL PUMP Pack contains the tubing sets and manifold and is intended to perform irrigation and aspiration during anterior segment cataract surgery. It is used with the WHITESTAR SIGNATURE or WHITESTAR SIGNATURE PRO Systems (“WHITESTAR SIGNATURE System(s)”). The DUAL PUMP Pack is sterilized using ethylene oxide and is designed for single use only.

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

Abbott Medical Optics Inc. (AMO) is submitting an Abbreviated 510(k) premarket notification for the Dual Pump Pack, Model OPO73, which is an accessory to the WHITESTAR SIGNATURE System(s); WHITESTAR SIGNATURE PRO, WHITESTAR SIGNATURE and AMO Ophthalmic Surgical Phacoemulsification Systems cleared under the premarket notifications K151636, K111697 and K060366 respectively. 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.

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Date of 510(k) Summary Preparation: March 23, 2016.

6.2 SUBJECT DEVICE

Trade/Proprietary Name: Dual Pump Pack – OPO73
Common Name: Phacoemulsification Pack, Fluidics Pack
Classification Name: Phacofragmentation System per 21 CFR 886.4670
Product Code: HQC
Regulatory Class: II

6.3 SUBSTANTIAL EQUIVALENCE SUMMARY

The Dual Pump Pack, Model OPO73, is a new optional phacoemulsification fluidics pack designed to facilitate anterior segment ophthalmic surgical procedures. The device is an optional accessory for use with the WHITESTAR SIGNATURE Phacoemulsification Systems (K151636, K111697 and K060366), which are designed for use in the surgical

setting for ophthalmologists with experience as phacoemulsification surgeons in the emulsification and removal of a cataractous lens from the eye.

The OPO73 Pack is claimed to be substantially equivalent to the following predicate:

- **Predicate Device:** FUSION Dual Pump Pack, Model OPO71 cleared on April 07, 2006 (K060366)

The predicate Phaco Pack, the DP (Dual Pump) Pack Disposable Tubing Set, later branded as Fusion Dual Pump Pack, Model OPO71, is designed for use in phacoemulsification procedures and provides all the tubing required for irrigation and aspiration. Both the subject device, OPO73 Pack and the predicate device, OPO71 Pack are designed for use with both the peristaltic pump and the venturi pump and share similarities in design, technology and functionality. The predicate device, Fusion Dual Pump Pack, Model OPO71 was first cleared as an accessory to the AMO Ophthalmic Surgical System under the premarket notification, K060366. The predicate device, OPO71 Pack was also cleared for use with the WHITESTAR SIGNATURE System, cleared under K111697 and WHITESTAR SIGNATURE PRO System, cleared under K151636.

Predicate Device to which Substantial Equivalence is claimed for the Dual Pump Pack, Model OPO73

510(k) Number	Date of FDA Clearance	Predicate Device/Accessory Name	510(k) Holder
K060366	April 07, 2006	DP Disposable Tubing Set, (Also branded as Fusion Dual Pump Pack, Model OPO71)	Abbott Medical Optics Inc.

6.4 DEVICE DESCRIPTION

The Dual Pump Pack, Model OPO73 is a single-use phacoemulsification pack that is an optional accessory for use with the WHITESTAR SIGNATURE Phacoemulsification Systems (K151636, K111697 and K060366), which are used to facilitate the emulsification and removal of a cataractous lens. The predicate device, the Fusion Dual Pump Pack, Model OPO71, is cleared for use with the WHITESTAR SIGNATURE Phacoemulsification Systems (K151636, K111697 and K060366) and was initially cleared for use as an accessory with the AMO Ophthalmic Surgical System under K060366. The predicate device, OPO71, Pack shares the same technology, intended use, and performance specifications as the subject device, OPO73 Pack.

6.5 TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE

Similar to the predicate device, the Dual Pump Pack, Model OPO73 supports peristaltic and venturi aspiration by means of a tubing interface in combination with an over-molded rear cover consisting of a diaphragm (also called the gasket with fluid channels) and a rear cover designed to generate fluid outflow from a patient's eye through aspiration tubing lines. The main technological characteristics in which the Dual Pump Pack, Model OPO73, is involved include irrigation and aspiration. All performance functions of the OPO73 Pack are identical to those of the predicate device, OPO71 (K060366).

The basic scientific concepts, energy source, design, intended use and FDA-recognized consensus standards used for performance testing of the Dual Pump Pack, Model OPO73, are identical to those of the predicate, FUSION Dual Pump Pack, Model OPO71 (K060366). The intended use of the Dual Pump Pack, Model OPO73 is anterior segment ophthalmic surgery, which is the same intended use as both predicate devices.

6.6 INDICATIONS FOR USE

The Indications for Use statement of the Dual Pump Pack, Model OPO73 is the following:

The DUAL PUMP Pack contains the tubing sets and manifold and is intended to perform irrigation and aspiration during anterior segment cataract surgery. It is used with the WHITESTAR SIGNATURE or WHITESTAR SIGNATURE PRO Systems (“WHITESTAR SIGNATURE System(s)”). The DUAL PUMP Pack is sterilized using ethylene oxide and is designed for single use only.

6.7 SUMMARY OF PERFORMANCE DATA

The Dual Pump Pack, Model OPO73, has undergone design verification and validation testing, which include parametric measurements testing and irrigation and aspiration testing. The test results demonstrate that the subject device, the Dual Pump Pack, Model OPO73, performs as safely and as effectively as the predicate device, the FUSION Dual Pump Pack, Model OPO71. During performance testing, all anterior segment ophthalmic surgery modes that require the OPO73 functionality, including irrigation/aspiration, were conducted; all tests passed and all acceptance criteria were met.

Components of the Dual Pump Pack, Model OPO73, have indirect contact with the patient by providing a fluid path for sterile Balanced Salt Solution (BSS) to enter the eye during surgery. Verification and validation testing was completed and all acceptance criteria were met, demonstrating that the OPO73 Pack has a similar safety, effectiveness and performance profile as the predicate device. Biocompatibility, sterilization, and evaluations of the materials that comprise the patient-contacting fluid path were performed to the following standards:

Standard Number	Standard Title
ISO 14971:2007	Medical devices – Application of risk management to medical devices
ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
AAMI/ANSI/ISO 10993-5:2009	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
ISO 10993-7:2008	Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals
ISO 10993-10:2010	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Standard Number	Standard Title
ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials
ISO 11135:2014	Sterilization of health care products – Ethylene Oxide – Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11979-5:2006	Ophthalmic implants – intraocular lenses – Part 5: Biocompatibility
ISO 14937:2009	Sterilization of health care products – general requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices.
ANSI/AAMI ST72:2002	Bacterial endotoxins – Tests methodologies, routine monitoring and alternatives to batch testing
ANSI/AAMI/ISO 11737-2:2009	Sterilization Of Medical Devices - Microbiological Methods - Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process.

6.8 SUMMARY OF CLINICAL TESTS

No clinical studies were deemed necessary to determine the safety and effectiveness of the Dual Pump Pack – OPO73.

6.9 CONCLUSIONS

The technological characteristics that determine the functionality and performance of the Dual Pump Pack, Model OPO73, are believed to be substantially equivalent to those for the cleared FUSION Dual Pump Pack, Model OPO71 predicate device (K060366). The Dual Pump Pack, Model OPO73, will be manufactured in compliance with FDA and ISO quality system requirements. The data from the non-clinical tests demonstrate that the device is as safe and as effective and performs as safely and as effectively as the legally marketed predicate devices. Verification and validation testing demonstrate that the functional requirements and system specifications will be met prior to commercial release.