DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 2, 2015

Abbott Medical Optics, Inc.
Priya Viswanathan, RAC
Sr. Specialist, Regulatory Affairs
1700 East Saint Andrew Place
Santa Ana, CA 92705

Re: K151783
Trade/Device Name: COMPACT INTUITIV Multiple-Use Pack, Model OP085
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: June 29, 2015
Received: July 1, 2015

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" (21CFR 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 Y. Alexander -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

Device Name
COMPACT INTUITIV Multiple-Use Pack, Model OPO85

Indications for Use *(Describe)*
The OPO85 is used with the COMPACT INTUITIV System. The OPO85 is sterilized using Ethylene Oxide and is designed for use up to 20 times. Following the first use, the user then follows cleaning and sterilization instructions specified below for up to 19 additional cleaning/sterilization cycles for a total of 20 uses when used according to the Instructions for Use.

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 Multiple-Use Pack, Model OPO85, which is an accessory to the COMPACT INTUITIV Phacoemulsification System cleared under the premarket notification, K133115. 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 92799-5162, USA
Contact Person:	Priya Viswanathan, RAC Sr. Specialist, Regulatory Affairs 1700 East St. Andrew Place Santa Ana, CA 92705 Tel: (714) 247-8670 Fax: (714) 566-3785 Email: Priya.Viswanathan@abbott.com
Date of 510(k) Summary Preparation:	June 29, 2015.

6.2 SUBJECT DEVICE

Trade/Proprietary Name:	Multiple-Use Pack - OPO85
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 Multiple-Use Pack, Model OPO85, 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 COMPACT INTUITIV Phacoemulsification System (K133115), which is 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 OPO85 Pack is claimed to be substantially equivalent to the following predicates:

- **Primary predicate:** Single-Use Fluidics Pack, Model OPO80 cleared on February 27, 2014 (K133115), designed for use with the COMPACT INTUITIV Phacoemulsification System (K133115).

- **Secondary predicate:** Sovereign Reusable Tubing Pack, Model OPO55 cleared on May 19, 1998, designed for use with the Sovereign Cataract Extraction Phacoemulsification System (K981116).

COMPACT INTUITIV System and its components were shown to be substantially equivalent to the Sovereign Compact Phacoemulsification System (K111446) and the Sovereign Compact Disposable Tubing Set, Model OPO61 (K981116) in the Premarket Notification, K133115.

The two predicate fluidics packs are both designed for use in phacoemulsification procedures to provide all the tubing required for irrigation and aspiration and share similarities in design, technology and functionality. The predicate devices to which substantial equivalence of the Multiple-Use Pack, Model OPO85 is claimed are listed below.

Predicate Devices to which Substantial Equivalence is claimed for the Multiple-Use Pack, Model OPO85

510(k) Number	Date of FDA Clearance	Predicate Device/Accessory Name	510(k) Holder
K133115	February 27, 2014	***Primary Predicate*** Single-Use Pack, OPO80	Abbott Medical Optics Inc.
K981116	May 19, 1998	***Secondary Predicate*** Reusable Tubing Pack, OPO55	Abbott Medical Optics Inc.

6.4 DEVICE DESCRIPTION

The Multiple-Use Pack, Model OPO85 is a reusable phacoemulsification pack that is an optional accessory for use with the COMPACT INTUITIV Phacoemulsification System (K133115), which is used to facilitate the emulsification and removal of a cataractous lens. The primary predicate device, the Single-Use Fluidics Pack, Model OPO80, is cleared for use with the COMPACT INTUITIV System and the secondary predicate device, the Sovereign Reusable Pack, Model OPO55, is cleared for use with the Sovereign Phacoemulsification System. Both the predicates share the same technology, intended use, and performance specifications as the subject device. The Multiple-Use Pack, Model OPO85, consists of a housing manifold, irrigation and aspiration tubing, irrigation inlet tubing connector, and a drain pump tubing connection. Like the secondary predicate device, Model OPO55, the OPO85 Pack is designed for reuse up to 19 times, for a total of 20 uses.

6.5 TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE

Similar to the predicate devices, the Multiple-Use Pack, Model OPO85 supports peristaltic aspiration by means of a tubing interface in combination with a molded cartridge designed to generate fluid outflow from a patient's eye through an aspiration tubing line. The main technological characteristics in which the Multiple-Use Pack, Model OPO85, is involved include irrigation and aspiration. All performance functions of the OPO85 Pack are identical to those of the primary predicate device, OPO80 (K133115). The performance functions for the reusability is identical to the secondary predicate device, OPO55 (K981116).

The basic scientific concepts, energy source, design, intended use and FDA-recognized consensus standards used for performance testing of the Multiple-Use Pack, Model OPO85, are identical to those of the primary predicate, Single-Use Fluidics Pack, Model OPO80 (K133115). The intended use of the Multiple-Use Pack, Model OPO85 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 Multiple-Use Pack, Model OPO85 is the following:

The OPO85 is used with the COMPACT INTUITIV System. The OPO85 is sterilized using Ethylene Oxide and is designed for use up to 20 times. Following the first use, the user then follows cleaning and sterilization instructions specified below for up to 19 additional cleaning/sterilization cycles for a total of 20 uses when used according to the Instructions for Use.

6.7 SUMMARY OF PERFORMANCE DATA

The Multiple-Use Pack, Model OPO85 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 Multiple-Use Pack, Model OPO85, performs as safely and as effectively as the predicate device, the Single-Use Pack, Model OPO80. During performance testing, all anterior segment ophthalmic surgery modes that require the OPO85 functionality, including irrigation/aspiration, were conducted; all tests passed and all acceptance criteria were met.

Components of the Multiple-Use Pack, Model OPO85, 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 OPO85 Pack has a similar safety, effectiveness and performance profile as the predicate device. Biocompatibility, sterilization, and reprocessing/re-sterilization 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
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
ANSI/AAMI ST79-2010	Comprehensive guide to steam sterilization and sterility assurance for health care facilities.
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 ST81:2004/2010	Sterilization of medical devices— Information to be provided by the manufacturer for the processing of resterilizable medical devices
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.
ANSI/AAMI/ISO 17665-1:2006	Sterilization Of Health Care Products -- Moist Heat -- Part 1: Requirements For The Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices.

All additional accessories required to use the OPO85 in the surgical setting, which include the Administration Set (P/N OM2505191) and Drain Bag (P/N OPO56), are the same as those used with the secondary predicate device, the Reusable Tubing Pack, Model OPO55, and have been cleared in previous 510(k) filings and are not within the scope of this premarket notification.

6.8 SUMMARY OF CLINICAL TESTS

No clinical studies were deemed necessary to determine the safety and effectiveness of the Multiple-Use Pack – OPO85.

6.9 CONCLUSIONS

The technological characteristics that determine the functionality and performance of the Multiple-Use Pack, Model OPO85, are believed to be substantially equivalent to those for the cleared Single-Use Pack, Model OPO80 primary predicate device (K133115) and Reusable Tubing Pack, Model OPO55 secondary predicate device (K981116). The Multiple-Use Pack, Model OPO85, 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.