OCT 15 2012

3. 510(K) SUMMARY

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 21CFR 807.92.

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510(k) Summary Preparation Date: June 11, 2012

Device that is the subject of this notification:

Trade/Proprietary Name: Laminar Flow Phacoemulsification Tip and Irrigation Sleeve (21G, Reusable)
Classification Name: Phacoemulsification Needle & Irrigation Sleeve (21 CFR 886.4670, Product code HQC)

The devices to which substantial equivalence are claimed are listed below in Table 3-1:

Table 3-1: Predicate Devices to which Substantial Equivalence is claimed

Predicate Device Name	Predicate Trade Name	510(k) Holder	510(k) Number	Clearance Date
AMO Irrigation Sleeve	Phaco Sleeve	AMO	K103023	05/24/2011
Laminar Flow Phaco Tip	Phaco Tip	AMO	K111882	10/24/2011

Table 3-2 compares features of the proposed Phaco Tips to those of the predicate device, The Laminar Flow Phaco Tip (cleared by the FDA under K111882). The Phaco Tip, subject of this premarket notification, is exactly the same in comparison to the predicate phaco tip except for the reusability. The Phaco Tips are compatible with all currently marketed AMO ultrasonic handpieces due to their hub size and the internal right-handed threading that

allows them to be screwed onto the distal end of any AMO handpiece. The only difference pertaining to reusability will be supported by additional testing highlighted in latter sections.

Aside from the difference highlighted in bold in the table below, the Phaco Tips have the same intended use, material, and functionality as its predicate and are therefore deemed to be substantially equivalent.

Table 3-2: Comparison Overview of the Phaco Tips to the Predicate Devices

Features and Characteristics	Proposed Device The Laminar Flow Phaco Tips	Predicate Device The Laminar Flow Phaco Tips (K111882)
Intended Use	With an Ultrasonic Handpiece during phacoemulsification surgery	Same
Description	The needle supplies ultrasonic movement at the tip to break up cataract material. The needle also supports an aspiration fluid path for removing cataract particles from the eye	Same
Handpiece Compatibility	All currently marketed AMO Ultrasonic Handpieces	Same
Patient Contact Material	Titanium Alloy (Ti 6Al-4V)	Same
Sterilization Method	Gamma Radiation	Same
Use	**Reusable**	**Single-use**
Thread	Right-Handed	Same
Tip Bevel Angle	Straight: 0-60° Curved: 30-45°	Same
Hub Design	Tapered with 5 lands	Same
Tip Length	Straight: 0.834" – 0.854" Curved: 0.840" – 0.860"	Same
Outer Diameter	21G 0.029" – 0.031"	Same
Inner Diameter	21G 0.020" – 0.022"	Same
Curve Range	0-24°	Same
Packaging	**With Irrigation Sleeve only**	**With Irrigation Sleeve only**

As the subject 21G Phaco Tips are intended to be packaged with the 21G Irrigation Sleeve, which is also the subject of this premarket notification; Table 3-3 referenced below compares the features of the proposed Irrigation sleeve with its respective predicate device, AMO Irrigation Sleeve, cleared by the FDA under K103023.

The Irrigation sleeve, subject of this premarket notification, is similar in comparison to the cleared Irrigation sleeve except for the reusability. The different gauge size (21G) compared to the predicate sleeve is mainly for achieving a smaller incision size during surgery. The smaller incision size thus enables the surgeons to use this device for Micro-implantation cataract surgeries. Additionally, the difference in flow rate specifications is to demonstrate a higher flow rate during surgery for the proposed Irrigation sleeve. Moreover, the difference in sleeve color (Light Blue and Orange vs. Yellow) is to differentiate between various sleeve gauge size offerings within the market (20G vs. 21G). Moreover, the difference in the sleeve color within the 21G size offering (Light Blue vs Orange) is only to offer the surgeon a preferred choice for use. Lastly, the proposed Irrigation sleeve will be provided as reusable

compared to AMO's disposable sleeve product offering. This additional reusability claim has been supported by testing highlighted in latter sections.

Aside from these differences highlighted in bold, in the table below, the Irrigation sleeves have the same intended use, material, and functionality as its predicate and are therefore deemed to be substantially equivalent. Additionally, Functional validation testing has been performed to demonstrate higher flow rate for the proposed Irrigation Sleeve. This testing can be found below under Section 16, Performance Testing – Bench.

Table 3-3: Comparison Overview of the Irrigation Sleeve to the Predicate Device

Features and Characteristics	Proposed Device The Laminar Flow Irrigation Sleeve	Predicate Device AMO Irrigation Sleeve (K103023)
Intended Use	To provide Irrigation during phacoemulsification surgery	Same
Description	The needle supplies ultrasonic movement at the tip to break up cataract material. The needle also supports an aspiration fluid path for removing cataract particles from the eye	Same
Contact Material	Silicone, Medical Grade	Same
Colorant	**Light Blue (Gray 61-801220, Blue 121 and White 177 Gum, odorless, stable, insoluble)** **Orange (Red 042 and Yellow 185 Gum, odorless, stable, insoluble)**	**Yellow 185 (Yellow Gum, odorless, stable, insoluble)**
Use	**Reusable**	**Single-use**
Sterilization Method	Gamma Radiation	Same
Flow Rate (cc/min)	**≥ 40**	**≥ 18**
Gauge Size	21G	19G – 23G
Length Range (inches)	1.0	0.75 – 1.50
Inner Diameter Range (inches)	0.050	0.030 – 0.065
Outer Diameter Range (inches)	0.063	0.050 – 0.080
Weight (grams/sleeve)	0.4	Same
Durometer (units)	80 ± 5	Same
Packaging	**With Phaco Tip OR With a Test Chamber**	**With Phaco Tip OR With a Test Chamber**

3.1 Device Description

Phacoemulsification (Phaco) is a technique used during cataract surgery to emulsify and extract a cataractous lens from the eye with an ultrasonic handpiece. The ultrasonic handpiece is connected to, and powered by a phacoemulsification system, which is identified in 21 CFR 886.4670 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."

The fragmentation needle, also referred to as a phaco tip, vibrates at an ultrasonic frequency and emulsifies the cataract when connected to an ultrasonic phacoemulsification handpiece. The fragmented tissue can then be aspirated and removed through the lumen of the tip. During a surgical procedure, irrigation solution, typically Balanced Salt Solution (BSS), is used to irrigate the eye and this is passed with the help of an Irrigation Sleeve. The Irrigation Sleeve directs the irrigation solution across the shaft of the phacoemulsification tip, allowing it to enter the eye during ocular surgery. This small molded component is placed over the Phacoemulsification tip. The proposed tips and irrigation sleeves are made of titanium and medical grade silicone respectively.

The subject of this 510(k) premarket notification is the Reusable Phacoemulsification Tips (Phaco Tips) & Irrigation Sleeves (Phaco Sleeves), which will be additions to the family of Disposable Laminar Flow Phacoemulsification Tips & Sleeves. The Phaco tips that are the subject of this 510(k) premarket notification have two different designs, straight and curved tip. The same two designs were the subject of the predicate device and have been cleared by the FDA under K111882 (AMO Laminar Flow Phaco Tips). These tips were cleared by the FDA for single use only and now AMO intends to introduce the reusable version of the same models into the market to offer a broad range of products to our customers. These tips will be compatible with all our currently marketed AMO ultrasonic handpieces, and will be made of the same surgical grade titanium as the predicate device. Moreover, these 21G tips will also be compatible with our 21G Irrigation Sleeves (Phaco Sleeve), which is the other subject device of this 510(k) premarket notification. The 21G Irrigation Sleeve will have a slightly different design as compared to the predicate device, which has been cleared under K103023 (AMO Irrigation Sleeve). The reduced gauge size (21G) is designed for use with the 21G Phaco tips. The proposed Light Blue and Orange sleeve will be made of the same medical grade silicone material as the predicate device (Yellow Sleeve), with a difference in the colorant to distinguish between the various AMO sleeve offerings in the market.

3.2 Indications for Use

The Laminar Flow Phacoemulsification Tips are used to break up (emulsify) the nucleus of a cataractous lens and remove the remaining nuclear fragments.
The Irrigation Sleeve is a device intended to direct irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.
The Phacoemulsification tip is intended for use in conjunction with the Irrigation Sleeve during ocular surgery.

3.3 Technological Characteristics

The technological characteristics of the Phaco Tips & Irrigation Sleeves are identical to those of the legally marketed predicate device also manufactured by AMO. With the exception of the reusability claim, the mechanism of action and technological features of the Phaco Tips & Irrigation Sleeves are the same as the predicate device with respect to materials, intended use, claims (except for reusability claim), clinical applications, patient population, method of operation, and performance specifications. Additional testing including Cleaning and

Autoclave validation has been performed to demonstrate reusability for both the proposed subject devices.

3.4 Summary of Performance Data

The proposed Phaco Tip has undergone various testing and is in compliance with applicable safety standards. Functional testing, sterilization validation, shelf life, packaging integrity, cleaning and autoclave validation has been performed and based on the results obtained, the proposed AMO Laminar Flow Phaco Tip is deemed to be substantially equivalent in its function and performance to the legally marketed predicate device, the AMO Laminar Flow Phaco Tips (K111882).

The proposed Irrigation sleeve has also undergone various testing and is in compliance with applicable safety standards. Functional testing, sterilization validation, shelf life, packaging integrity, cleaning and autoclave validation has been performed and based on the results obtained, the proposed AMO Laminar Flow Irrigation Sleeve is deemed to be substantially equivalent in its function and performance to the legally marketed predicate device, AMO Irrigation sleeve (K103023).

Based on the results obtained, the performance testing was considered successful and demonstrates that Phaco Tips & Irrigation Sleeve perform equivalently to the predicate devices with respect to safety and effectiveness.

The various performance testing performed for our Phaco Tips and Irrigation Sleeves are in compliance with the applicable standards listed below in Table 3-4.

Table 3-4: Standards Used in Testing of Phaco Tip, Irrigation Sleeve & Test Chamber

Standard Number	Document Title
ISO 11137-1:2006/(R)2010	Sterilization of Health Care Products – Radiation – Part 1: Requirements for Development, Validation, and Routine Control of Sterilization Process for Medical Devices
ISO 11137-2:2006	Sterilization of Health Care Products – Radiation – Part 2 Establishing the Sterilization Dose
ISO 11137-3: 2006/ (R) 2010	Sterilization of Health Care Products – Radiation – Part 3: Guidance on Dosimetric Aspects
ANSI/AAMI ST79: 2010 & A1:2010	Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
AAMI TIR12:2010	Designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers
TIR30:2011	A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
ISO 17664:2004	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.
ANSI/AAMI/IEC 80601-2-58:2008	Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery

3.5 Summary of Non-Clinical Data

Biocompatibility studies have been performed for the Phaco Tips and Irrigation Sleeves and results have shown the material used in these devices to be biocompatible and safe for use during the cataract surgery. Additionally Non-clinical animal studies were performed for the Straight and Curved Laminar Flow Phaco Tips along with the Irrigation Sleeves. Both studies demonstrate that Phaco tips and sleeves are safe and effective for human use and that they perform well with our various AMO phacoemulsification systems and handpieces and pose no additional risks.

Both these Non-Clinical testing (Animal and Biocompatibility testing, irrespective of their colorants) demonstrate similar effectiveness and performance profiles with respect to their predicates and hence they are deemed to be substantially equivalent to their respective predicate devices.

3.6 Overall Summary

The information presented in this 510(k) premarket notification demonstrates that the Laminar Flow Phaco Tips & Irrigation Sleeve are substantially equivalent to the legally marketed predicate device, also manufactured by AMO. The technological characteristics, material, intended use, and manufacturing processes remain unchanged for the Phaco Tips & Irrigation Sleeve when compared to their predicates. AMO concludes that these devices are safe, effective, and substantially equivalent to their predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

OCT 15 2012

Abbott Medical Optics Inc.
% Mr. Abbas Bohra
Regulatory Affairs Specialist
1700 E. St. Andrew Place
Santa Ana, CA 92705

Re: K121721
Trade/Device Name: Laminar Flow Phaco Tips and Irrigation Sleeve (21G, Reusable)
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: September 6, 2012
Received: September 6, 2012

Dear Mr. Bohra:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

for Kesia Alexander

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

2. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121721

Device Name: Laminar Flow Phacoemulsification Tip and Irrigation Sleeve (21G, Reusable)

Indications For Use:

The Laminar Flow Phacoemulsification Tips are used to break up (emulsify) the nucleus of a cataractous lens and remove the remaining nuclear fragments.
The Irrigation Sleeve is a device intended to direct irrigation solution across the shaft of a phacoemulsification tip, allowing the solution to enter the eye during ocular surgery.
The Phacoemulsification tip is intended for use in conjunction with the Irrigation Sleeve during ocular surgery.

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)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K121721