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K111882

4. 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.

Applicant:

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Contact Person:

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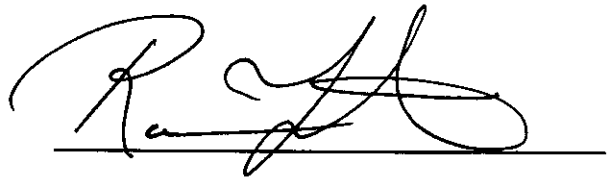

Date the 510(k) Summary Preparation: June 30, 2011

Device that is the subject of this notification:

Trade/Proprietary Name: Laminar Flow Phaco Tip
Classification Name: Phacoemulsification Needle

The devices to which substantial equivalence is claimed:

Table 4-1: Predicate Device to Which Substantial Equivalence is Claimed

Predicate Device Name	Predicate Trade Name	510(k) Holder	510(k) Number	Clearance Date
AMO Profinesse III Needle	Phaco Tip	AMO	K951462	06/15/1995

4.1 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 – referenced in the aforementioned definition is the focus of this 510(k) premarket notification. Phaco tips vibrate at an ultrasonic frequency and emulsify a 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), used to irrigate the eye also passes through the hollow opening of the phaco tip.

The subject of this 510(k) premarket notification is for the Phacoemulsification Tips (Phaco Tips) that are additions to the family of Laminar Flow Phacoemulsification Tips, of which there are two proposed designs: a straight tip and a curved tip. Both Phaco Tip models will be marketed as single-use devices, will be compatible with all currently marketed AMO ultrasonic handpieces, and will be made of the same surgical grade titanium as the predicate device; the AMO Profinesse III Needle cleared under the AMO Profinesse III Handpiece 510(k), K951462.

4.2 Indications for Use

The Laminar Flow Phacoemulsification Needles (Tips) are designed to emulsify and excise cataract tissue in ophthalmic microsurgical procedures.

4.3 Technological Characteristics

The technological characteristics of the Phaco Tips are identical to those of the legally marketed predicate device also manufactured by AMO. The mechanism of action and technological features of the Phaco Tips are the same as the predicate device with respect to materials, intended use, claims, clinical applications, patient population, method of operation, and performance specifications.

4.4 Summary of Performance Data

Performance testing was conducted to demonstrate that the Phaco Tips perform equivalently to the predicate device with respect to safety and effectiveness. Functional validation testing, sterilization, packaging, and biocompatibility assessments all demonstrate that the proposed device, the Phaco Tips, are substantially equivalent in their function and performance to the legally marketed predicate device, the AMO Profinesse III Needle (K951462).

4.5 Non-Clinical Tests

Non-clinical animal studies were performed for the Straight and Curved Laminar Flow Phaco Tips. Both studies demonstrate that the tips perform well with various AMO

phacoemulsification systems and handpieces and pose no additional risks. The results of the animal studies also indicate that the Phaco Tips are safe and effective.

4.6 Summary

The information presented in this 510(k) premarket notification demonstrates that the Laminar Flow Phaco Tips 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 when compared to the predicate. AMO concludes that this device is safe, effective, and substantially equivalent to its predicate device as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Abbott Medical Optics Inc.
c/o Ms. Rosanne Yetemian
Regulatory Affairs Specialist
1700 E. St. Andrew Place
Santa Ana, CA 92705

Re: K111882
Trade/Device Name: Laminar Flow Phaco Tips
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: October 21, 2011
Received: October 24, 2011

Dear Ms. Yetemian:

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,

Kesia Alexander

for 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

3. INDICATIONS FOR USE STATEMENT

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

Device Name: Phacoemulsification Needles (Tips)

Indications For Use:

The Laminar Flow Phacoemulsification Needles (Tips) are used to break up (emulsify) the nucleus of a cataractous lens and remove the remaining nuclear fragments.

Prescription Use ✓ (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

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