OCT 0 8 2008

K081861 Vitrectomy Cutter/Aspiration Device and Irrigation Sleeve – Request for Information
Advanced Medical Optics, Inc.

K081681

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 21 CFR 807.92.

The applicant is:	Advanced Medical Optics, Inc. 1700 E. St. Andrew Place Santa Ana CA 92705, USA
Est. Registration number:	2020664
The contact person is:	Evelyn De La Vega Regulatory Affairs Specialist Tel: (714) 247-8487 Fax: (714) 247-8784
Date:	September 18, 2008
Device Trade Name:	AMO™ 20GA Vitrectomy Cutter and Irrigation Sleeve, AMO™ 20GA Vitrectomy Cutter, AMO™ 20GA Irrigation Sleeve.
Device Classification Name:	Vitreous Aspiration and Cutting Device, and Irrigation Sleeve
Classification:	Class II, Tier II

The devices to which substantial equivalence is claimed:

510(k) Number	Clearance Date	Device
K950287	March 3, 1995	UnuVit and 4422CE (Midlabs)

DEVICE DESCRIPTION

The Vitrectomy Cutter is a device intended to remove vitreous matter from the eye and the Irrigation Sleeve provides irrigation during the vitrectomy procedure. The vitrectomy mode is used to cut and remove vitreous matter from the anterior segment of the eye during secondary intraocular lens implantation following vitreous loss associated with trauma or during primary cataract surgery. It can also be used to provide vitreous cutting in the posterior segment by enabling surgeons to remove vitreous matter for the treatment of various posterior segment conditions.

The device has been placed in Class II under section 513 of the Federal Food, Drug, and Cosmetic Act. The device is a Tier II and the appropriate panel is the Ophthalmic devices Panel. Its classification maybe found in Part 886 of 21 CFR (Code of Federal Regulations); it's specifically identified under regulation number 886.4150.

INDICATIONS FOR USE

The Vitrectomy Cutter is a device intended to remove vitreous matter from the eye and the Irrigation Sleeve provides irrigation during the vitrectomy procedure.

SUMMARY

The physical and performance characteristics of the vitrectomy cutter and the irrigation sleeve are substantially equivalent to those of the predicate devices. The products will be manufactured in compliance with both FDA (QSR) and ISO standards and have demonstrated to be safe and effective for the indicated use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 0 8 2008

Advanced Medical Optics, Inc.
c/o Evelyn De La Vega
1700 E. St. Andrew Place
P.O. Box 25162
Santa Ana, CA 92705

Re: K081681
Trade/Device Name: AMO™ 20GA Vitrectomy Cutter and Irrigation Sleeve NGP0020,
AMO™ 20GA Vitrectomy Cutter NGP0020A,
AMO™ 20GA Irrigation Sleeve NGP0020B
Regulation Number: 21 CFR 886.4150
Regulation Name: Vitreous Aspiration and Cutting instrument
Regulatory Class: II
Product Code: MLZ
Dated: August 25, 2008
Received: August 26, 2008

Dear Evelyn De La Vega:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

INDICATION FOR USE STATEMENT

510(k) number (if known): K081681

Device Name: AMO™ 20GA Vitrectomy Cutter and Irrigation Sleeve,AMO™ 20GA Vitrectomy Cutter, AMO™ 20GA Irrigation Sleeve

Indication for Use:

The Vitrectomy Cutter is a device intended to remove vitreous matter from the eye and the Irrigation Sleeve provides irrigation during the vitrectomy procedure. These devices are for use with the Whitestar Signature™ System.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number K081681