



K081545

OCT 02 2008

## 5.0 510(k) SUMMARY

This 510(k) summary is being submitted in accordance with the requirements of 21 CFR 807.92(c).

### 1. Submitter's name, address, telephone number, contact person, and date summary prepared:

- a. Applicant: Advanced Medical Optics, Inc.  
1700 E. St. Andrew Place  
Santa Ana, CA 92705
- b. Contact Person: Kim Regis  
Manager, Regulatory Affairs Projects  
1700 E. St. Andrew Place  
Santa Ana, CA 92705  
Ph: 714.247.8564  
Fax: 714.247.8677
- c. Date Summary Prepared: May 30, 2008

### 2. Name of device, including trade name and classification name:

- a. Trade/Proprietary Name: One Series™ Ultra cartridge
- b. Classification Name: Intraocular Lens Guide
- c. Device Classification: Class I per 21 CFR 886.4300
- d. Product Code: KYB

### 3. Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Company: Advanced Medical Optics, Inc. (AMO®)  
Device: AMO® PhacoSert™ cartridge  
510(k): K961242  
Date Cleared: June 17, 1996

Company: IntraLuminal Therapeutics, Inc.  
Device: Safe-Cross® Deflecting Catheter  
510(k): K031692  
Date Cleared: August 22, 2003

**4. A description of the device that is the subject of the 510(k), including explanation of how the device functions, basic scientific concepts, significant physical and performance characteristics (design, material, physical properties):**

The One Series™ Ultra cartridge is used to fold and assist in the insertion of a TECNIS® 1-Piece soft acrylic intraocular lens (IOL) into the eye following cataract extraction. The cartridge, Model 1VIPR30 is a single-use component composed of polypropylene which is injection molded and coated with a lubricious coating. The cartridge is provided sterile. The IOL is loaded into the proximal portion of the cartridge using forceps. The cartridge is then placed in a reusable titanium handpiece, which advances the IOL through the tube section of the cartridge and delivers it into the eye.

**5. Statement of intended use:**

The One Series™ Ultra cartridge is used to fold and assist in the insertion of a TECNIS® 1-Piece soft acrylic intraocular lens (IOL) into the eye.

**6. Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device.**

The technological characteristics of the One Series™ Ultra cartridge were compared to those of the predicate devices and were found to be equivalent with respect to materials, method of sterilization, intended use, and/or mode of operation.

**7. Brief summary of nonclinical tests and results:**

Bench testing and biocompatibility testing were conducted which verified that the material and performance characteristics (folding, delivery, and retention of IOL cosmetic, dimensional, and optical properties) associated with the One Series™ Ultra cartridge were equivalent to that of the predicate devices.

**8. Conclusions:**

AMO has demonstrated through its evaluation of the One Series™ Ultra cartridge that the device is equivalent to the predicate devices with respect to intended use, technological characteristics, and safety and effectiveness.



OCT 02 2008

Advanced Medical Optics, Inc.  
c/o Ms. Kim Regis  
Manager, Regulatory Affairs Projects  
1700 E. St. Andrew Place  
Santa Ana, CA 92705

Re: K081545  
Trade Name: ONE SERIES™ ULTRA Cartridges  
Regulation Number: 21 CFR 886.4300  
Regulation Name: Intraocular lens guide  
Regulatory Class: I  
Product Code: KYB  
Dated: September 25, 2008  
Received: September 26, 2008

Dear Ms. Regis:

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

**CDRH INDICATIONS FOR USE**

510(k) Number (if known): K081545

Device Name(s): One Series™ Ultra cartridge  
Indications for Use:

Used to fold and assist in inserting TECNIS® 1-Piece intraocular lenses into the eye.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Kerri Alexander*  
(Division Sign-Off)

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Division of Ophthalmic Ear,  
Nose and Throat Devices

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