K063694

Bausch & Lomb

MAR 07 2007

510(k) Summary

Akreos Single Use Insertion Device, Model AI-28

Submitter Information	Owner:	Bausch & Lomb, Incorporated 180 Via Verde San Dimas, CA 92886
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	Contact:	Nanette Canepa Associate Manager, Global Regulatory Affairs
Date Prepared	December 12, 2006	
Subject device name	Trade name: Akreos Single Use Insertion Device, Model AI-28 Common name: Lens insertion guide Classification name: Intraocular lens guide (21CFR 886.4300, Product Code KYB)	
Predicate device	Passport foldable lens placement system	

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Subject device description

Akreos Single Use Insertion Device, Model AI-28, previously known as Hydroport SI, is validated for folding and delivering the Bausch & Lomb one-piece Akreos Advanced Optics Aspheric Intraocular Lens (IOL) into the eye during cataract surgery. Future IOL models may also by qualified with the Akreos Single Use Insertion Device following fold and recovery validation studies.

The device provides a small tubular pathway in which the Akreos Advanced Optics Aspheric Lens can be placed into the eye with one continuous forward motion. The Akreos Single Use Insertion Device consists of two parts: a syringe shaped tube (includes lens loading deck and lens cap) with a plunger, and a transition cell.

The Akreos Single Use Insertion Device is a sterile (EtO), disposable plastic device, designed for single use only.

Technological characteristics

The similarities between the Akreos Single Use Insertion Device, Model AI-28 and the Passport foldable lens placement system are the overall design, components, intended use, operating principle, folding direction of the lens, cartridge design, sterilization methods and component materials with the exception of the plunger material.

The change in plunger material of the subject device has not altered the fundamental scientific technology of the predicate device.

Intended use

The intended use for the Akreos Single Use Insertion Device, Model AI-28 is to fold and deliver a Bausch & Lomb IOL into the eye during normal small incision cataract surgery.

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Labeling

The labeling for the Akreos Single Use Insertion Device, Model AI-28 and the Passport foldable lens placement system differ in the type of intraocular lens specified for use.

These differences in the labeling that specify use, do not affect safety and effectiveness of the device when used as labeled because each insertion device is specifically made to fit the size and shape of the indicated intraocular lens.

Substantial Equivalence discussion

Substantial equivalence is based on non-clinical performance data that show that the subject device met the acceptance criteria for fold and recovery testing of the Akreos Aspheric Optic IOL using the same principle of operation as the predicate device. Stability testing for the plunger material met the acceptance criteria showing no significant shifts in tensile and flexural properties following sterilization. Therefore, the effectiveness is demonstrated for the indicated use of the subject device.

~~The Akreos Single Use Insertion Device, Model AI-28 was shown~~ to be safe using the results of the biocompatibility testing for the polypropylene material as well as polyphthalamide, the new plunger material. Sterilization and Shelf-life test results confirm that the subject device is substantially equivalent to the marketed predicate device.

Conclusion

Based on the 510(k) summary and the information provided herein, we conclude that the modified device is substantially equivalent to the predicate device, is safe and effective under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bausch & Lomb
c/o Ms. Nanette Canepa
Associate Manager, Global Regulatory Affairs
180 E. Via Verde Drive
San Dimas, CA 91773

MAR 07 2007

Re: k063694
Trade/Device Name: Akreos Single Use Insertion Device
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: KYB
Dated: February 7, 2007
Received: February 8, 2007

Dear Ms. Canepa:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,

M B Eydelman, MD

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

Indications for Use

510(k) Number (if known):	K063694
Device Name:	Akreos Single Use Insertion Device
Indications For Use:	The Akreos Single Use Insertion Device should only be used to fold and deliver those IOL models that allow use of this injector in their approved labeling.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 Ear,
Nose and Throat Devises

510(k) Number K063694