

5. 510(K) SUMMARY

MAR 27 2007

510(k) Summary

This summary document is being prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

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Date Summary Prepared: October 9, 2006

Device Subject to this 510(k):

Trade Name: Monarch® III IOL Delivery System
(D Cartridge and H4 Handpiece)
Common Name: Intraocular Lens Guide
Classification Name: 21 CFR 886.4300

1. Predicate Devices:

The legally marketed device(s) to which we are claiming substantial equivalence are:

<u>510(k) Number</u>	<u>Device</u>
K003768	Monarch® II IOL Delivery System (A & C Cartridges)
K001157	Monarch® II IOL Delivery System (B Cartridge)

2. Device Description:

The Monarch© III IOL Delivery System is a modification to the previously cleared Alcon Monarch(r) II IOL Delivery System (K003768) consisting of a disposable cartridge and reusable handpiece. The Monarch II cartridges are designated as A, B, and C, and feature various nozzle tip sizes that correspond to the various AcrySof® IOL models. As with the cleared cartridges, the

Monarch© III IOL Delivery System presented in this submission utilizes a one-piece disposable cartridge (designated as D) with progressive folding in combination with a reusable handpiece (H4). This new cartridge possesses the same basic inner lumen design and lens guiding mechanisms as the existing Monarch*) II A, B, and C cartridges, but differs in nozzle tip sizing.

3. Indications for Use:

The MONARCH® III IOL Delivery System is used for implantation of ALCON® qualified ACRYSOF® intraocular lenses into the eye following cataract removal.

4. Brief Summary of Nonclinical Test and Results:

Alcon has provided a Statement of Conformance (Attachment J) that the Monarch® III IOL Delivery System Cartridge D and Handpiece H4 intended to be introduced, will conform in all respects with the requirements set forth in the FDA Intraocular Lens Guidance Document (Draft released 10/14/1999) Section C. Mechanical Testing, 5. Folding and Injection Testing prior to marketing the product.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alcon Research, Ltd.
Ms. Catherine G. Goble
Senior Manager, Regulatory Affairs
6201 South Freeway
Fort Worth, TX 76134

MAR 27 2007

Re: K063155
Trade Name: Monarch[®] III IOL Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: KYB
Dated: February 28, 2007
Received: March 1, 2007

Dear Ms. Goble:

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,



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): K063155

Device Name: Monarch III IOL Delivery System


Indications For Use:

The MONARCH® III IOL Delivery System is used for implantation of ALCON® qualified ACRYSOF® intraocular lenses into the eye following cataract removal.

Prescription Use YES AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (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)


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

510(k) Number K063155