BAUSCH + LOMB

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K123736

5 510(k) Summary

Submitter: Bausch & Lomb, Inc.
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MAY 16 2013

Date Prepared: December 4, 2012

Trade name: Crystalsert Delivery System

Classification Name: Intraocular lens guide (21 CFR 886.4300)

Predicate Devices: K082944 Crystalsert Crystalens Delivery System

Device Description: The Crystalsert Delivery System is a sterile, single-use device used to fold and insert an intraocular lens through surgical procedure into a human eye. The system provides a tubular pathway through an incision over the iris, allowing delivery of an IOL into the capsular bag.

Indications for Use: The Crystalsert Delivery System is intended to be used to fold and deliver the Crystalens accommodating intraocular lens and other intraocular lenses identifying the Crystalsert Delivery System in their approved labeling.

Comparative Analysis: The Crystalsert Delivery System has been demonstrated to be equivalent to the predicate device for its intended use.

Functional/Safety Testing: The Crystalsert Delivery System has successfully undergone functional testing and was found to deliver IOLs in conformance with the requirements set forth in ISO 11979-3, section 5.

Conclusion: The Crystalsert Delivery System is substantially equivalent to the predicate device.

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Characteristic	Predicate K082944 Crystalsert Crystalens Delivery System	Crystalens Delivery System (Proposed Device)
Indications for use	The Crystalsert Crystalens delivery system is intended to fold and deliver the Crystalens (AT-52SE, AT-50SE, HD520 and HD500) accommodating intraocular lens into the capsular bag.	The Crystalsert delivery system is intended to be used to fold and deliver the Crystalens accommodating intraocular lens and other intraocular lenses identifying the Crystalsert delivery system in their approved labeling.
Contraindications	None	None
Materials	Body, drawer, plunger: polypropylene Spring: stainless steel	Body, drawer, plunger: polypropylene Spring: stainless steel
Single use?	Single use	Single use
Sterile?	Sterile	Sterile
How sterilized	Ethylene oxide	Ethylene oxide
Sterility assurance level	10^{-6}	10^{-6}
Shelf life	12 months	12 months

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

May 16, 2013

Bausch & Lomb Inc.
% Mr. Jason Smith
Global Regulatory Affairs Manager
30 Enterprise, Suite 450
Aliso Viejo, CA 92656

Re: K123736
Trade/Device Name: Crystalsert Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular lens guide
Regulatory Class: Class I (reserved)
Product Code: MSS
Dated: April 4, 2013
Received: April 5, 2013

Dear Mr. Smith:

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 contact 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. 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 Y Alexander -S

for 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

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Indications for Use Statement

510(k) Number (if known):

Device Name: Crystalsert Delivery System

Indications for Use:

The Crystalsert Delivery System is intended to be used to fold and deliver the Crystalens accommodating intraocular lens and other intraocular lenses identifying the Crystalsert delivery system in their approved labeling.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(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)

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(Division Sign-Off)

Division of Ophthalmic and Ear, Nose

and Throat Devices

510(k) Number_K123736_____