



Food and Drug Administration  
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May 22, 2015

Bausch + Lomb Inc.  
Ms. Joyce Zhong  
Regulatory Affairs Specialist  
50 Technology Drive  
Irvine, CA 92618

Re: K151102  
Trade/Device Name: Bausch + Lomb Injector System  
Regulation Number: 21 CFR 886.4300  
Regulation Name: Intraocular Lens Guide  
Regulatory Class: Class I  
Product Code: MSS  
Dated: April 23, 2015  
Received: April 24, 2015

Dear Ms. Zhong:

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 Industry and Consumer Education 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" (21 CFR 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 Industry and Consumer Education 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 -A**

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

## 5 Indications for Use Statement

510(k) Number (if known):

Device Name: Bausch + Lomb Injector System

Indications for Use:

The Bausch + Lomb Injector System is indicated for the folding and insertion of Bausch + Lomb intraocular lenses cleared or approved for use with this IOL Injector system.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

## **6 510(k) Summary**

This summary document has been prepared in accordance with section 21 CFR 807.92(c).

The submitter of the 510(k) is:

Joyce Zhong  
Regulatory Affairs Specialist  
Bausch & Lomb, Inc.  
50 Technology Drive  
Phone: 949-398-5594  
Fax: 949-398-5764

Date Summary Prepared: April 23, 2015

### **1. Subject Device:**

Trade name: Bausch + Lomb Injector System  
Common Name: Intraocular lens Guide  
Classification Name: 21 CFR 886.4300

### **2. Predicate Device:**

K131958, Bausch + Lomb Injector System

### **3. Device Description:**

The Bausch + Lomb Injector System is used for folding and delivering validated IOLs into the eye. The system is composed of two items: a single-use, sterile, disposable cartridge and a reusable handpiece. The handpiece has two elements: a plunger and a body. The cartridge snaps into the handpiece.

### **4. Indications for Use:**

The BLIS is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the BLIS in their approved labeling.

This is the same exact indications for use as the predicate device.

**5. Brief Summary of Nonclinical Test and Results:**

Performance bench testing was completed on the Bausch + Lomb Injector System and results show the system to be in conformance with the requirements set forth in respective standards.

**6. Comparative Analysis**

A table comparing the proposed device to the predicate device is provided below.

**Table 6-1: Comparison of Predicate Device to the Proposed Bausch + Lomb Injector System**

Characteristic	K131958, (Predicate Device) Bausch + Lomb Injector System	(Proposed Device) Bausch + Lomb Injector System
Indications for use	The BLIS is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the BLIS in their approved labeling.	The BLIS is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the BLIS in their approved labeling.
Contraindications	None	None
Anatomical site	Eye	Eye
Injector configuration (reusable)	Titanium body, plunger tip, knob; stainless steel plunger shaft, plunger threads	Titanium body, plunger tip, knob; stainless steel plunger shaft, plunger threads
Injector configuration (single use)	Coated polyamide cartridge	Coated polyamide cartridge
How is the device used	The IOL is placed in the loading cartridge. The cartridge is snapped into the handpiece. The screw plunger advances the IOL through the cartridge, which folds the IOL and advances it into the eye.	The IOL is placed in the loading cartridge. The cartridge is snapped into the handpiece. The screw plunger advances the IOL through the cartridge, which folds the IOL and advances it into the eye.
Single use?	Handpiece: No Cartridge: Yes	Handpiece: No Cartridge: Yes
Is the product sterile	Handpiece: shipped nonsterile, to be cleaned and sterilized/resterilized by user  Cartridge: shipped sterile	Handpiece: shipped nonsterile, to be cleaned and sterilized/resterilized by user  Cartridge: shipped sterile
How sterilized	Handpiece: steam (by user)  Cartridge: Ethylene oxide (by manufacturer)	Handpiece: steam (by user)  Cartridge: Ethylene oxide (by manufacturer)

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50 Technology Drive, Irvine CA 92618  
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<b>Characteristic</b>	<b>K131958, (Predicate Device) Bausch + Lomb Injector System</b>	<b>(Proposed Device) Bausch + Lomb Injector System</b>
Coating	Handpiece: None  Cartridge: Hydrophilic coating (Medicoat A)	Handpiece: None  Cartridge: Hydrophilic coating (Medicoat A)
How Supplied	Handpiece: single  Cartridge: Packs of 10	Handpiece: single  Cartridge: Packs of 10

**7. Conclusion**

The Bausch + Lomb Injector System is substantially equivalent to the predicate device.