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](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](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](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)

___________________________________________________________

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**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>K131958, (Predicate Device) Bausch + Lomb Injector System</th>
<th>(Proposed Device) Bausch + Lomb Injector System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indications for use</td>
<td>The BLIS is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the BLIS in their approved labeling.</td>
<td>The BLIS is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the BLIS in their approved labeling.</td>
</tr>
<tr>
<td>Contraindications</td>
<td>None</td>
<td>None</td>
</tr>
<tr>
<td>Anatomical site</td>
<td>Eye</td>
<td>Eye</td>
</tr>
<tr>
<td>Injector configuration (reusable)</td>
<td>Titanium body, plunger tip, knob; stainless steel plunger shaft, plunger threads</td>
<td>Titanium body, plunger tip, knob; stainless steel plunger shaft, plunger threads</td>
</tr>
<tr>
<td>Injector configuration (single use)</td>
<td>Coated polyamide cartridge</td>
<td>Coated polyamide cartridge</td>
</tr>
<tr>
<td>How is the device used</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Single use?</td>
<td>Handpiece: No, Cartridge: Yes</td>
<td>Handpiece: No, Cartridge: Yes</td>
</tr>
<tr>
<td>Is the product sterile</td>
<td>Handpiece: shipped nonsterile, to be cleaned and sterilized/resterilized by user Cartridge: shipped sterile</td>
<td>Handpiece: shipped nonsterile, to be cleaned and sterilized/resterilized by user Cartridge: shipped sterile</td>
</tr>
<tr>
<td>How sterilized</td>
<td>Handpiece: steam (by user) Cartridge: Ethylene oxide (by manufacturer)</td>
<td>Handpiece: steam (by user) Cartridge: Ethylene oxide (by manufacturer)</td>
</tr>
</tbody>
</table>
7. Conclusion
The Bausch + Lomb Injector System is substantially equivalent to the predicate device.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>K131958, (Predicate Device) Bausch + Lomb Injector System</th>
<th>(Proposed Device) Bausch + Lomb Injector System</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coating</td>
<td>Handpiece: None</td>
<td>Handpiece: None</td>
</tr>
<tr>
<td></td>
<td>Cartridge: Hydrophilic coating (Medicoat A)</td>
<td>Cartridge: Hydrophilic coating (Medicoat A)</td>
</tr>
<tr>
<td>How Supplied</td>
<td>Handpiece: single</td>
<td>Handpiece: single</td>
</tr>
<tr>
<td></td>
<td>Cartridge: Packs of 10</td>
<td>Cartridge: Packs of 10</td>
</tr>
</tbody>
</table>