Bausch & Lomb, Inc
Ms. Rekha Janarthanan
Regulatory Affairs Manager
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122

Re: K192005
Trade/Device Name: Bausch + Lomb PreVue Inserter for enVista Preloaded
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: September 3, 2019
Received: September 4, 2019

Dear Ms. Janarthanan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.


For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Charles Chiang -S

for Tieuvi Nguyen, Ph.D.
Acting Division Director
DHT1A: Division of Ophthalmic Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known)
K192005

Device Name
Bausch + Lomb PreVue Inserter for enVista Preloaded

Indications for Use (Describe)
The Bausch + Lomb PreVue inserter for enVista preloaded is indicated for folding and inserting of enVista IOLs (Model MX60PL) and IOL models approved for use with this IOL insertion device as indicated in the IOL approved labeling.

Type of Use (Select one or both, as applicable)
☑ Prescription Use (Part 21 CFR 801 Subpart D)
☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter: Bausch & Lomb, Inc.
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122

Contact Person: Rekha Janarthanan
Regulatory Affairs Manager
Phone: 636-226-3095
Email: rekha.janarthanan@bausch.com

Trade name: Bausch + Lomb PreVue Inserter for enVista preloaded

Classification Name: Intraocular lens guide (21 CFR 886.4300)

FDA Product Code: MSS

Predicate Devices: 1. Bausch & Lomb Injector System (K113852)
2. Bausch & Lomb Injector System, BLIS (K131958)

Device Description: The Bausch + Lomb PreVue inserter for enVista preloaded is a sterile, single-use device used to fold and insert an intraocular lens (MX60PL) through surgical procedure into a human eye. The Inserter provides a tubular pathway through an incision over the iris, allowing delivery of an IOL into the capsular bag.

Indications for Use: The Bausch + Lomb PreVue inserter for enVista preloaded is indicated for folding and inserting of enVista IOLs (Model MX60PL) and IOL models approved for use with this IOL insertion device as indicated in the IOL approved labeling.

Comparative Analysis: The Bausch + Lomb IOL Inserters have been demonstrated to be equivalent to the predicate devices for their intended use.

Functional/Safety Testing: The Bausch + Lomb IOL Inserters have successfully undergone functional testing and are found to deliver the Bausch + Lomb IOLs in conformance with the requirements set forth in ISO 11979-3.

Conclusion: The Bausch + Lomb IOL Inserters are substantially equivalent to the predicate devices.
### a. Technological Similarities

<table>
<thead>
<tr>
<th>Indications for Use</th>
<th>Predicate – Bausch + Lomb IOL Injector, INJ100 (K113852)</th>
<th>Predicate – Bausch + Lomb Injector System, BLIS (K131958)</th>
<th>Subject Device - Bausch + Lomb PreVue Inserter</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Bausch + Lomb IOL Injector is indicated for folding and injection of Bausch + Lomb IOLs approved for use with this injector.</td>
<td>The BLIS 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.</td>
<td>The Bausch +Lomb PreVue inserter for enVista preloaded is indicated for folding and inserting of enVista IOLs (Model MX60PL) and IOL models approved for use with this IOL insertion device as indicated in the IOL approved labeling.</td>
<td></td>
</tr>
<tr>
<td>How device is used</td>
<td>The IOL is placed in the loading chamber. A plunger pushes the IOL into the tip, which folds the IOL. Pushing the plunger further advances the IOL out through the tip 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>
<td>The preloaded IOL shuttle is snapped into loading chamber of the PreVue inserter. The screw plunger advances the IOL through the shuttle into the cartridge which folds the IOL and advances it into the eye.</td>
</tr>
</tbody>
</table>
| Injector/Inserter Components | • ABS Body  
• ABS Plunger  
• Polyamide Cartridge  
• Medicoat A Coating | • Titanium Body  
• Stainless Steel Plunger Shaft  
• Titanium Plunger Tip  
• Polyamide Cartridge  
• Medicoat A Coating | • ABS Body  
• Polyamide Cartridge  
• ABS Thread Bushing  
• Polyphthalamide Plunger (this uses Al- 28 as predicate)  
• ABS Spindle  
• Medicoat A Coating |
| Single Use | Injector: Yes  
Cartridge: Yes | Injector: No  
Cartridge: Yes | Inserter: Yes  
Cartridge: Yes |
| Sterilization Method | Ethylene Oxide | • Cartridge: Stainless Steel  
• Injector: Shipped Non-Sterile. Steam Sterilized by User | Ethylene Oxide |
| Shelf Life | 24 months | Cartridge: 24 months  
Injector: Reusable | 12 months |

### b. Non Clinical Testing

<table>
<thead>
<tr>
<th>Test</th>
<th>Standards</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Delivery Verification</td>
<td>ISO 11979-3: 2012</td>
<td>Pass</td>
</tr>
<tr>
<td>Dioptic Power and Image quality Post delivery</td>
<td>ISO 11979-2: 2012</td>
<td>Pass</td>
</tr>
<tr>
<td>Lens Dimensions Post Delivery</td>
<td>ISO 11979-3: 2012</td>
<td>Pass</td>
</tr>
<tr>
<td>Surface and Bulk Homogeneity</td>
<td>ISO 11979-3: 2012</td>
<td>Pass</td>
</tr>
<tr>
<td>PreVue Inserter Cosmetic Inspection</td>
<td>N/A</td>
<td>Pass</td>
</tr>
<tr>
<td>Coating transfer study</td>
<td>ISO 10993-1</td>
<td>Pass</td>
</tr>
<tr>
<td>Particle counting study</td>
<td>ISO 10993-1</td>
<td>Pass</td>
</tr>
</tbody>
</table>
Biocompatibility and Baseline Stability | ISO 10993-1 | Pass
---|---|---
Leachable Extractions | ISO 10993-18 | Pass

**Chemical Evaluation**
- Evaluation and rationale for inclusion in “family grouping” of similar devices | ANSI/AAMI/ISO 11135 | Pass

**Sterilization Validation Adoption**
- Product Adoption Analysis | EN ISO 11135:2014 | Pass

**EO Residuals**

**Bacterial Endotoxin**
- Bacterial Endotoxin test | ANSI/AAMI ST72:2011/(R)2016 | Pass

**Packaging Verification**
- Injector Sealing Validation Report | ASTM F88-09 and ASTM F1929 | Pass

c. No clinical testing was performed on the subject device.

d. **Summary of Nonclinical tests and Results:**

Bench tests, laboratory tests, and evaluations were completed on the proposed B+L PreVue Inserter for enVista Preloaded. No animal or clinical testing was required for this submission.

Device functional performance testing all passed and demonstrates equivalence to predicate device. EO/ ECH residual transfer and Endotoxin validation testing passed. Sterilization evaluation, packaging verification, biocompatibility evaluation all met requirements and demonstrated equivalence to the predicate device. All results support the conclusion that the proposed device PreVue Inserter for enVista Preloaded demonstrates substantial equivalence to the predicate devices.

A risk analysis was conducted for the PreVue Inserter in accordance with EN ISO 14971: 2012. The Hazard and Risk Assessment follows a systematic approach by a cross-functional team to help prioritize problem prevention efforts for the PreVue, considering possible failures of components and subsystems of the product and the resulting effects. The technique employed used the bottom-up approach that is typical of Failure Mode and Effects Analysis (FMEA), while capturing all results in an FMEA table. The document is used in the design, development, and testing of PreVue to identify risks and track mitigation efforts.

Product safety risks are assessed in terms of probability that harm may occur, taking into consideration normal use and reasonably foreseeable misuse conditions. As well as, historical complaint data and applying other risk management elements as per EN ISO 14971. Each residual risk was evaluated for acceptability through a risk/benefit analysis. All identified foreseeable hazards and potential failure modes have been subjected to risk/benefit analysis and it has been determined that the medical benefits of the intended use outweigh the overall residual risk.