K131958 Bausch + Lomb Injector System

JAN - 9 2014

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:

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Date Summary Prepared: January 7, 2014

1. Subject Device:

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

2. Predicate Devices:

K113852, Bausch + Lomb IOL Injector
K063155, Alcon Monarch III IOL Delivery 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..

Note: This is almost the same indications for use as the predicate Bausch + Lomb IOL Injector (K113852). The differences between the two indications are differences in describing which Bausch + Lomb IOLs are appropriate for use with these injectors. The subject device adds more detail to this description than the subject K113852 device. This difference is not critical to the intended therapeutic or surgical use of the device.

5. Brief Summary of Nonclinical Test and Results:

The proposed Bausch + Lomb Injector System was evaluated using cleaning, sterilization, sterilization residual, shipping and handling, biocompatibility, and bench testing. Cleaning validation covered the manual and automated cleaning processes described in the labeling for the Bausch + Lomb Injector System Handpiece. Sterilization validation included the autoclave methods described in the labeling for the Bausch + Lomb Injector System Handpiece and the ethylene oxide process for the Bausch + Lomb Injector System Cartridge. Ethylene oxide residual testing for a device equivalent to the Bausch + Lomb Injector System Cartridge was included in the 510(k).

Shipping and handling validations were performed on both the Bausch + Lomb Injector System Handpiece and Cartridge. Stability testing validated the Bausch + Lomb Injector System Cartridge over the shelf life of the device.

Biocompatibility testing was performed the Bausch + Lomb Injector System Handpiece and cartridge, and both were found to be biocompatible.

Bench testing was performed on both components of the Bausch + Lomb Injector System to demonstrate compliance with ISO 11979-3, Mechanical Properties.

6. Comparative Analysis

A table comparing the proposed device to the predicate devices is provided on the following page.

7. Conclusion

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

Comparison of Predicate Devices to the Proposed Bausch + Lomb Injector System

Characteristic	K113852 Bausch + Lomb IOL Injector	K063155 Alcon Monarch III Delivery System	Bausch+ Lomb Injector System (Proposed Device)
Indications for Use	Folding and injection of Bausch + Lomb IOLs that have the use of this injector in their labeling.	Handpiece: For use with Alcon Monarch III cartridges as specified in the table below (product number 8065977763) for the surgical implantation of Alcon Foldable IOLs. Cartridge: Implantation of Alcon qualified ACrySoft Foldable IOLs. No unqualified lenses should be used with the Monarch III IOL Delivery System.	The BLIS is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the BLIS in their approved labeling.
Contraindications	None	None	None
Anatomical site	Eye	Eye	Eye
Injector configuration (reusable)	Not applicable	Titanium shaft with a titanium screw plunger	Titanium body, plunger tip, knob; stainless steel plunger shaft, plunger threads
Injector configuration (single use)	A syringe-shaped ABS body, coated polyamide tip , ABS push plunger and polypropylene cartridge.	Cartridge	Coated polyamide cartridge
How is the device used?	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.	The IOL is placed in the loading cartridge. The catridge 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 catridge 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	Yes	Handpiece: No Cartridge: Yes	Handpiece: No Cartridge: Yes

Characteristic	K113852 Bausch + Lomb IOL Injector	K063155 Alcon Monarch III Delivery System	Bausch+ Lomb Injector System (Proposed Device)
Is the product sterile?	Yes	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	Ethylene oxide	Handpiece: steam (by user) Cartridge: Ethylene oxide (by manufactuerer)	Handpiece: steam (by user) Cartridge: Ethylene oxide (by manufacturer)
Coating	Hydrophilic coating (Medicoat A)	Handpiece: None Cartridge: Hydrophilic coating	Handpiece: None Cartridge: Hydrophilic coating (Medicoat A)
How Supplied	Packs of 10	Handpiece: single Cartridge: packs of 10	Handpiece: single Cartridge: Packs of 10

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

January 9, 2014

Bausch + Lomb
c/o Mr. Jason Smith
Manager, Global Regulatory Affairs
30 Enterprise, Suite 450
Aliso Viejo, CA 92656

Re: K131958
Trade Name: Bausch + Lomb Injector System, BLIS
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I (reserve)
Product Code: MSS
Dated: November 22, 2013
Received: November 25, 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,

Deborah L. Falls -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

5 Indications for Use Statement

510(k) Number (if known): 131958

Device Name: Bausch + Lomb Injector System (BLIS)

Indications for Use:

The BLIS is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the BLIS 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)

Claudine H. Krawczyk
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