DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

July 6, 2016

Bausch and Lomb, Inc.
Dr. Joyce Zhong
Regulatory Affairs Specialist
50 Technology Drive
Irvine, CA92618

Re: K161012
Trade/Device Name: Easy-load Lens Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: June 3, 2016
Received: June 6, 2016

Dear Dr. 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 Alexander

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: Easy-Load Lens Delivery System

Indications for Use:

The Easy-Load Lens Delivery System is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the Easy-Load Lens 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)

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: April 7, 2016

1. Subject Device:

Trade name: Easy-Load Lens Delivery System
Common Name: Intraocular lens Guide
Classification Name: 21 CFR 886.4300

2. Predicate Device:

Primary Predicate Device	K132481	Easy-Load Lens Delivery System	EZ-28
Secondary Predicate Device	K131958	Bausch + Lomb Injector System	BLIS-X1

3. Device Description:

The Easy-Load Lens Delivery System is used for folding and delivering a Bausch + Lomb three-piece silicone IOL into the eye. An IOL is placed into the loading area and the drawer is closed. This compresses the IOL. The plunger is advanced until it stops at a detent position. The distal end is filled with viscoelastic or balanced salt solution and placed through an incision into the eye. The haptic puller is used to place the leading haptic in the correct loading position. Once the tip is in the eye, the plunger is advanced until the lens is fully expressed into the capsular bag.

4. Indications for Use:

The Easy-Load Lens Delivery System is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the Easy-Load Lens Delivery System in their approved labeling.

The indications for use of the proposed device are the same as the primary predicate device.

5. Brief Summary of Nonclinical Test and Results:

Nonclinical tests listed below were completed on the proposed Easy-Load Lens Delivery System (Model EZ-24) and results show the system to be in conformance with the requirements set forth by accepted ISO standards (ISO 11979-2, ISO 11979-3, and ISO 11135) where applicable.

Item	TEST	Acceptance Criteria	RESULTS
Function Performance	(Before and after insertion) IOL surface & bulk homogeneity	Free from surface and bulk defects and all edges should appear smooth when viewed at 10X magnification	Pass
	(Before and after insertion) IOL lens power	The diopter power of the lenses shall be within the allowed tolerance	Pass
	(Before and after insertion) IOL image quality	The image quality of the lenses shall meet or exceed the minimum resolution group element of the Air Force target specified in the protocol.	Pass
	(Before and after insertion) IOL dimensions	The lenses must meet the dimensional requirements specified in the protocol.	Pass
	IOL delivery outcome	The IOLs do not flip over upon delivery; The IOL must exit inserter upon completion of delivery; No cosmetic defects to the IOL's haptic from folding and/or delivery	Pass
	Damage to insertion device	No damage to the insertion device due to lens delivery	Pass
	Lubricant transfer study	No detectable transfer	Pass
	Particle study	Comparable to or lower than control	Pass
Sterilization verification	Comparative Resistance Performance Determination	For a given exposure time the average recovery of viable test organisms from biological indicators placed within the barrel of either the EZ-24 or the EZ-28 shall differ by no more than one logarithm of the average of the values determined for both inserters. Alternatively, the average recovery of viable test organisms from biological indicators placed within the barrel of the EZ-24 may be less than the average recovery of viable test organisms from biological indicators placed within the barrel of the EZ-28 inserters	Pass
	EO transfer test	≤ 0.5µg EO per IOL	Pass
	Endotoxin test	< 0.2 EU/device	Pass
Packaging verification	Plunger push force and cartridge detachment testing	Cartridge detachment force is greater than the force to disengage the plunger from the detents in the injector body.	Pass

6. Comparative Analysis

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

Table 6-1: Comparison of Primary Predicate Device (Model EZ-28) to the Proposed Easy-Load Lens Delivery System (Model EZ-24)

Characteristic	**Primary Predicate Device EZ-28 (K132481)**	**Proposed Device EZ-24**
Indications for use	The Easy-Load Lens Delivery System is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the Easy-Load Lens Delivery System in their approved labeling.	The Easy-Load Lens Delivery System is indicated for the folding and injection of Bausch + Lomb intraocular lenses identifying the Easy-Load Lens Delivery System in their approved labeling.
Contraindications	None	None
Anatomical site	Eye	Eye
Injector configuration	Body, drawer, haptic puller, plunger	Body, cartridge, drawer, haptic puller, plunger, bearing
Materials	Body, drawer, haptic puller, plunger: Polypropylene	Body: drawer, haptic puller, plunger, bearing: Polypropylene Cartridge: Polyimide
How is the device used	An IOL is placed into the loading area and the drawer is closed. This compresses the IOL. The plunger is advanced until it stops at a detent position. The distal end is filled with viscoelastic or balanced salt solution and placed through an incision into the eye. The haptic puller is used to place the leading haptic in the correct loading position. Once the tip is in the eye, the plunger is advanced until the lens is fully expressed into the capsular bag.	An IOL is placed into the loading area and the drawer is closed. This compresses the IOL. The plunger is advanced until it stops at a detent position. The distal end is filled with viscoelastic or balanced salt solution and placed through an incision into the eye. The haptic puller is used to place the leading haptic in the correct loading position. Once the tip is in the eye, the plunger is advanced until the lens is fully expressed into the capsular bag.
Single use?	Yes	Yes
Is the product sterile?	Sterile	Sterile
How sterilized	Ethylene oxide	Ethylene oxide
Sterility assurance level	10^{-6}	10^{-6}
Shelf life	12 months	12 months

7. Conclusion

The results obtained from nonclinical tests performed on the proposed Easy Load Lens Delivery System have demonstrated that the proposed device is as safe, as effective, and performs at least as safely and effectively as the predicate devices, therefore the proposed Easy Load Lens Delivery System is substantially equivalent to the predicate devices.