December 11, 2017

Bausch & Lomb, Inc
Gary Rauvola
Regulatory Affairs Manager
3365 Tree Ct.
Industrial Blvd.
St. Louis, Missouri 63122

Re: K173480
Trade/Device Name: Crystalsert Lens Delivery System
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I
Product Code: MSS
Dated: November 2, 2017
Received: November 13, 2017

Dear Gary Rauvola:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Denise L. Hampton -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Crystalsert Lens Delivery System CI-26

Indications for Use *(Describe)*
The Crystalsert Delivery System is intended to be used to fold and deliver the Crystalens accommodating intraocular lens and other intraocular lenses identifying the Crystalsert Delivery System in their 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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:

Gary Rauvola
Regulatory Affairs Manager
Bausch + Lomb
3365 Tree Court Industrial Blvd
St. Louis, MO. 63122
Phone: 636-226-3402

Date Summary Prepared: November 02, 2017

1. Subject Device:

Trade name:	Crystalsert Lens Delivery System
Common Name:	Intraocular lens Guide
Classification Name:	21 CFR 886.4300

2. Predicate Device:

Primary Predicate Device	K132593	Crystalsert Lens Delivery System	CI-28

3. Device Description:

The Crystalsert Delivery System is a device used for folding and delivering the Crystalens accommodating intraocular lens and other IOLs indicating use of the Crystalsert Delivery System in their approved labeling into the eye. The Crystalsert Delivery System consists of a syringe shaped body and tip with a plunger and drawer. The Crystalsert Delivery System is a sterile, disposable plastic device, with a small tubular pathway in which the lens can be placed into the eye with one continuous motion, designed for single use only.

4. Indications for Use:

The Crystalsert Delivery System is intended to be used to fold and deliver the Crystalens accommodating intraocular lens and other intraocular lenses identifying the Crystalsert Delivery System in their approved labeling.

The indications for use of the proposed device are identical to the primary predicate device.

5. Brief Summary of Nonclinical Tests and Results:

Bench tests, laboratory tests, and evaluations were completed on the proposed B+L Crystalsert Lens Delivery System (Model CI-26). No animal or clinical testing was required for this submission. Please refer to the summary table shown below.

Item	Test	Results
Function Performance	(Before and after insertion) IOL surface & bulk homogeneity	Pass
	(Before and after insertion) IOL lens power	Pass
	(Before and after insertion) IOL image quality	Pass
	(Before and after insertion) IOL dimensions	Pass
	IOL delivery outcome	Pass
	Damage to insertion device	Pass
	Coating transfer study	Pass
	Particle counting study	Pass
Sterilization verification	Evaluation and rationale for inclusion in "family grouping" of similar devices per ISO11135:2014 and AAMI TIR 28:2009	Pass
Packaging verification	Evaluation and rationale for inclusion in "family grouping" of similar devices.	Pass
Product shelf life	Evaluation and rationale for inclusion in "family grouping" of similar devices for a one-year shelf life.	Pass
Biocompatibility	Evaluation and rationale was performed per ISO 10993-1:2009 and ISO 10993-18:2005. Components are either the same part or considered to be materially equivalent to parts in the predicate device. As such, no additional biocompatibility testing was warranted or conducted.	Pass
EO/ ECH residuals transfer test	Lab testing per ISO 10993-7:2008 with protocols and acceptance criteria previously reviewed by FDA.	Pass
Bacterial Endotoxin Validation pre- and post-sterilization	Lab testing per EN ISO 13485:2012	Pass

Device functional performance testing all passed and demonstrates equivalence to predicate device. EO/ ECH residual transfer tests all passed. Endotoxin validation testing passed. Sterilization evaluation, packaging verification, shelf-life evaluation, biocompatibility evaluation all met requirements and demonstrated equivalence to the predicate device. All results support the conclusion that the proposed device (Model CI-26) is as safe and as effective, and therefore equivalent to the predicate device (Model CI-28).

6. Comparative Analysis

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

Table 6-1: Comparison of Crystalsert Lens Delivery System Predicate Device (Model CI-28) to the Proposed Minor Modification (Model CI-26)

Characteristic	Primary Predicate Device CI-28 (K132593)	Proposed Device CI-26
Indications for use	The Crystalsert Delivery System is intended to be used to fold and deliver the Crystalens accommodating intraocular lens and other intraocular lenses identifying the Crystalsert Delivery System in their approved labeling.	The Crystalsert Delivery System is intended to be used to fold and deliver the Crystalens accommodating intraocular lens and other intraocular lenses identifying the Crystalsert Delivery System in their approved labeling.
Contraindications	None	None
Anatomical site	Eye	Eye
Injector configuration	Body, drawer, plunger, bearing	Body, cartridge, drawer, plunger, bearing, haptic guide
Materials	Body, drawer, plunger, bearing: Polypropylene	Body: drawer, 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. 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 haptic guide is removed and distal end is filled with viscoelastic or balanced salt solution and placed through an incision into the eye. 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/ SAL	Ethylene oxide/ 10^{-6}	Ethylene oxide/ 10^{-6}
Shelf life	12 months	12 months

7. Conclusion

The proposed Crystalsert Lens Delivery System CI-26 is substantially equivalent to the CI-28 predicate device.