October 10, 2024

Bausch & Lomb Incorporated
Renee Stoffel
Associate Director, Regulatory Affairs
1400 North Goodman Street
Rochester, New York 14609

Re: K242389
Trade/Device Name: EyeGility™ Inserter for Preloaded enVista® IOLs
Regulation Number: 21 CFR 886.4300
Regulation Name: Intraocular Lens Guide
Regulatory Class: Class I, reserved
Product Code: MSS
Dated: August 12, 2024
Received: August 12, 2024

Dear Renee Stoffel:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

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,

Jinny Liu

For Bennett Walker, Ph.D.
Assistant 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K242389

Device Name
EyeGility™ Inserter for Preloaded enVista® IOLs

Indications for Use *(Describe)*
The EyeGility Inserter for enVista preloaded is indicated for folding and inserting of enVista 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 Incorporated 1400 North Goodman Street Rochester, NY 14609
Contact Person:	Renee Stoffel Associate Director, Regulatory Affairs (651) 392-4619
Date Prepared:	September 20, 2024
Trade Name:	EyeGility™ Inserter for Preloaded enVista® IOLs
Classification Name:	Intraocular lens guide (21 CFR 886.4300)
FDA Product Code:	MSS
Predicate Devices:	Primary Predicate Device Bausch + Lomb PreVue Inserter for enVista Preloaded (K192005) Predicate Device Bausch + Lomb IOL Injector, INJ 100 (K113852)
Device Description:	The EyeGility Inserter is a sterile, single-use device used to fold and insert an intraocular lens 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 EyeGility Inserter for enVista preloaded is indicated for folding and inserting of enVista IOL models approved for use with this IOL insertion device as indicated in the IOL approved labeling.
Summary of Performance and Non-clinical Testing:	The EyeGility Inserter has successfully undergone functional testing in conformance with the requirements set forth in ISO 11979-3. Additional nonclinical testing information is provided in Table 1. All acceptance criteria were met, demonstrating the subject device is substantially equivalent to the predicate devices.
Clinical Testing:	No clinical testing was completed in support of the subject device.
Comparative Analysis:	The EyeGility Inserter has been demonstrated to be equivalent to the predicate devices for its intended use. Table 2 includes a detailed comparison of the subject and predicate devices.
Conclusion:	The EyeGility Inserter is substantially equivalent to the predicate devices.

Table 1. Nonclinical Testing Summary

Testing Category	Test	Standards	Results
Delivery Verification Testing and Stability Testing	Fold and Recovery Test	ISO 11979-3	Pass
	Dioptric Power and Image Quality Post Delivery	ISO 11979-2	Pass
	Lens Dimensions Post Delivery	ISO 11979-3	Pass
	Surface and Bulk Homogeneity	ISO 11979-3	Pass
	Cosmetic Inspection	N/A	Pass
Biocompatibility	Biocompatibility Assessment	ISO 10993-1	Pass
	Particulate Study	ISO 10993-1	Pass
	Coating Transfer Study	ISO 10993-1	Pass
	Leachable Extractions	ISO 10993-18	Pass
EO Sterilization	Validation Product Adoption Analysis	ISO 11135	Pass
EO Residuals	ETO/ECH Transfer Engineering Study	ISO 10993-7	Pass
Bacterial Endotoxin	Bacterial Endotoxin Test	ANSI/AAMI ST72	Pass
Packaging	Transport Stability Testing	ISO 11607-1 ISO 11979-6 ASTM F2096	Pass

Table 2. Comparison of the subject and predicate device.

Technological Similarities	Subject Device – EyeGility Inserter	Primary Predicate Device - Bausch + Lomb PreVue Inserter (K192005)	Predicate Device - Bausch + Lomb IOL Injector, INJ100 (K113852)
Indications For Use	The EyeGility Inserter for enVista preloaded is indicated for folding and inserting of enVista IOL models approved for use with this IOL insertion device as indicated in the IOL approved labeling.	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.	The Bausch + Lomb IOL Injector is indicated for folding and injection of Bausch + Lomb IOLs approved for use with this injector
How device is used	The preloaded IOL shuttle is snapped into loading chamber of the enVista inserter body. The push-type plunger advances the IOL through the shuttle into the cartridge which folds the IOL and advances it into the eye.	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.	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.

Technological Similarities	**Subject Device – EyeGility Inserter**	**Primary Predicate Device - Bausch + Lomb PreVue Inserter (K192005)**	**Predicate Device - Bausch + Lomb IOL Injector, INJ100 (K113852)**
Inserter Components	ABS Body Pebax Cartridge (Medicoat A) PPA Plunger Silicone Soft tip	ABS Body Pebax Cartridge (Medicoat A) PPA Plunger ABS Thread Bushing and Screw Spindle	ABS Body ABS Plunger Polyamide Cartridge Medicoat A Coating
Single Use	Injector: Yes Cartridge: Yes	Inserter: Yes Cartridge: Yes	Inserter: Yes Cartridge: Yes
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Shelf Life	22 months	36 months	24 months