March 25, 2026

Bausch and Lomb Incorporated
Emily Smith
Sr. Specialist, Regulatory Affairs
3365 Tree Court Industrial Boulevard
St. Louis, Missouri 63122

Re: K252052
Trade/Device Name: Stellaris Elite™ vision enhancement system (BL11145, BL14455, BL15455, SE14565, SE15565, SE14565E, SE15565E)
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE, HQF
Dated: February 12, 2026
Received: February 12, 2026

Dear Emily 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 (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

CLAUDINE H. KRAWCZYK -S

Claudine Krawczyk
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K252052

Please provide the device trade name(s).

Stellaris Elite™ vision enhancement system (BL11145, BL14455, BL15455, SE14565, SE15565, SE14565E, SE15565E)

Please provide your Indications for Use below.

The Bausch + Lomb Stellaris Elite™ vision enhancement system is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations.

The Bausch + Lomb Stellaris Elite™ vision enhancement system configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

1 General Information

Submitter:	Contact Person:
Bausch + Lomb Inc. 3365 Tree Court Industrial Blvd. St Louis, MO 63122 General Telephone: 636-226-3017	Emily Smith 3365 Tree Court Industrial Blvd. St Louis, MO 63122 636-226-3271 emily.smith@bausch.com

Preparation Date: March 25, 2026

2 Names

Device Name:	Stellaris Elite™ vision enhancement system (BL11145, BL14455, BL15455, SE14565, SE15565, SE14565E, SE15565E)
Classification Names:	Phacofragmentation Unit, Vitreous Aspiration and Cutting Instrument
Common Name:	Ophthalmic surgical system for cataract and vitreo-retinal surgery
CFR References:	21 CFR 886.4670, 21 CFR 886.4150, 21 CFR 886.4390
Product Codes:	HQC, HQE, HQF

3 Predicate Devices

K240169 – Stellaris Elite™ vision enhancement system, Bausch + Lomb
K153168 – Bi-Blade Vitrectomy Cutter, Medical Instrument Development Laboratories, Inc (MidLabs)

4 Product Description

The Bausch + Lomb Stellaris Elite™ vision enhancement system is comprised of an integrated ophthalmic microsurgical system designed for use in anterior and posterior segment surgery including phacofragmentation, vitreous aspirating, cutting, and endoillumination. Additionally, the Stellaris Elite™ vision enhancement system may be configured with a laser module intended for retinal photocoagulation and laser trabeculoplasty.

A selection of disposable single-use procedure packs is available for use with the system. These packs contain the necessary tubing to facilitate delivery and removal of air and fluids to and from the patient as well as a selection of components (cannulas, cutters, probes, drapes, etc.) that facilitate the surgical procedure. The items are arranged for physician convenience and may be presented as a group intended to support all the needs of a procedure or packaged singularly to allow the physician greatest flexibility.

The Bi-Blade™+ vitrectomy cutters are powered by a pneumatic pulse that operates the guillotine style cutter. The cutter has dual side ports and an aspiration channel that allows for aspiration during surgery. Each Bi-Blade™+ vitrectomy cutter is packaged and sterilized by gamma radiation.

5 Indications for Use

The Bausch + Lomb Stellaris Elite™ vision enhancement system is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Bausch + Lomb Stellaris Elite™ vision enhancement system configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

The Bausch + Lomb Anterior Vitrectomy Cutter Packs are intended for use with a Bausch + Lomb Microsurgical System for vitrectomy during anterior segment surgery. The Posterior Vitrectomy Cutter Packs are intended for use with a Bausch + Lomb Microsurgical System for vitrectomy during posterior segment surgery. The Combined Vitrectomy Cutter Packs are intended for use with a Bausch + Lomb Microsurgical System for both vitrectomy during posterior segment surgery and for phacoemulsification of an opacified crystalline lens during anterior segment surgery.

6 Summary of Technological Characteristics and Substantial Equivalence Discussion

The following tables compare the subject devices, Stellaris Elite™ vision enhancement system and Bi-Blade™+ vitrectomy cutter, to the predicate devices with respect to the characteristics used to determine substantial equivalence.

Stellaris Elite™ vision enhancement system			
Characteristic	**Predicate Device: Stellaris Elite™ vision enhancement system**	**Subject Device: Stellaris Elite™ vision enhancement system**	**Equivalency Analysis**
Manufacturer	Bausch + Lomb	Bausch + Lomb	Same
US 510(k) Premarket Notification	K240169	K252052	N/A
Product Codes	HQC, HQE, HQF	HQC, HQE, HQF	Same
Regulation Number	21 CFR 886.4670 21 CFR 886.4150 21 CFR 886.4390	21 CFR 886.4670 21 CFR 886.4150 21 CFR 886.4390	Same
Device Class	II	II	Same
Intended Use	Ophthalmic surgery	Ophthalmic surgery	Same

Stellaris Elite™ vision enhancement system			
Characteristic	**Predicate Device: Stellaris Elite™ vision enhancement system**	**Subject Device: Stellaris Elite™ vision enhancement system**	**Equivalency Analysis**
Indications for Use	The Bausch + Lomb Stellaris Elite™ vision enhancement system is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Bausch + Lomb Stellaris Elite™ vision enhancement system configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.	The Bausch + Lomb Stellaris Elite™ vision enhancement system is intended for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. The system is designed for use in both anterior and posterior segment surgeries. It provides capabilities for phacoemulsification, coaxial and bimanual irrigation/aspiration, bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. The Bausch + Lomb Stellaris Elite™ vision enhancement system configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.	Same
System Functions/ Procedures	- Phacoemulsification - Irrigation/Aspiration - Vitrectomy - Fluid/Air Exchange - Coagulation - Endoillumination - Fragmentation - Air Forced Infusion - Viscous Fluid Control (VFC) - Laser Photocoagulator	- Phacoemulsification - Irrigation/Aspiration - Vitrectomy - Fluid/Air Exchange - Coagulation - Endoillumination - Fragmentation - Air Forced Infusion - Viscous Fluid Control (VFC) - Laser Photocoagulator	Same
Hardware Design	- System main console - Primary (integrated) foot control with battery, wall charger, backup cable - System power cord - Mayo tray - Air hose - Zero level bottle hanger - Remote control	- System main console - Primary (integrated) foot control with battery, wall charger, backup cable - System power cord - Mayo tray - Air hose - Zero level bottle hanger - Remote control	Same
Graphical User Interface, Software and Components	Console, a graphical user interface screen and software to control the system functionality, surgical modules, a primary (integrated) foot control, infrared remote control, procedure packs and pouches	Console, a graphical user interface screen and software to control the system functionality, surgical modules, a primary (integrated) foot control, infrared remote control, procedure packs and pouches	Same
Software Operating System	Windows 10 IoT Enterprise 22H2 Long Term Support Channel (LTSC)	Windows 10 IoT Enterprise 22H2 Long Term Support Channel (LTSC)	Same

Stellaris Elite™ vision enhancement system			
Characteristic	**Predicate Device: Stellaris Elite™ vision enhancement system**	**Subject Device: Stellaris Elite™ vision enhancement system**	**Equivalency Analysis**
Electrical Input	AC: 100-240V; 50/60 Hz	AC: 100-240V; 50/60 Hz	Same
Primary (Integrated) Foot Control	- Wireless control (10m standard range) - Corded, low voltage connection to system - Wall Charger - 3.6v battery (lithium) - four side buttons, and a center Foot Pedal with two axes of movement to control two linear functions (pitch and yaw)	- Wireless control (10m standard range) - Corded, low voltage connection to system - Wall Charger - 3.6v battery (lithium) - four side buttons, and a center Foot Pedal with two axes of movement to control two linear functions (pitch and yaw)	Same
Remote Control	- Anterior use only - Wireless pointing device providing line of sight operation using an IR transmitter - Provides operation up to 15 feet from display console - Powered from standard AA battery	- Anterior use only - Wireless pointing device providing line of sight operation using an IR transmitter - Provides operation up to 15 feet from display console - Powered from standard AA battery	Same
Automated IV Pole	Automated capable of lifting two (2) 500 ml glass bottles of Balanced Salt Solution. Controlled via touch screen entry, remote control, Primary (Integrated) Foot Control, or directly via buttons on the back of the system	Automated capable of lifting two (2) 500 ml glass bottles of Balanced Salt Solution. Controlled via touch screen entry, remote control, Primary (Integrated) Foot Control, or directly via buttons on the back of the system	Same
Coagulation	- Linear Mode and Fixed Control - Maximum Output Range: 7.5 Watts, 0.274 A - Nominal @ 100 ohms - Frequency: 1 MHz nominal	- Linear Mode and Fixed Control - Maximum Output Range: 7.5 Watts, 0.274 A - Nominal @ 100 ohms - Frequency: 1 MHz nominal	Same
Ultrasound	- Continuous ultrasound - Pulsed ultrasound - Fixed pulse ultrasound - Single burst ultrasound - Multiple burst ultrasound - Dual Linear Ultrasound - Linear Power, Linear Pulse ultrasound - Linear Power, Linear Duty Cycle ultrasound - Dual Linear Multiple Burst ultrasound - Variable Power Multiple Burst ultrasound - Variable Power Linear Burst ultrasound	- Continuous ultrasound - Pulsed ultrasound - Fixed pulse ultrasound - Single burst ultrasound - Multiple burst ultrasound - Dual Linear Ultrasound - Linear Power, Linear Pulse ultrasound - Linear Power, Linear Duty Cycle ultrasound - Dual Linear Multiple Burst ultrasound - Variable Power Multiple Burst ultrasound - Variable Power Linear Burst ultrasound	Same

Stellaris Elite™ vision enhancement system			
Characteristic	**Predicate Device: Stellaris Elite™ vision enhancement system**	**Subject Device: Stellaris Elite™ vision enhancement system**	**Equivalency Analysis**
Aspiration	Linear, Fixed, or Dual Linear control of vacuum with maximum vacuum of 660 mmHg	Linear, Fixed, or Dula Linear control of vacuum with maximum vacuum of 660 mmHg	Same
Irrigation	Gravity feed from I/V bottle with pinch valve On/Off control via Foot Pedal	Gravity feed from I/V bottle with pinch valve On/Off control via Foot Pedal	Same
Fluid/Air Exchange, Pressurized Infusion and Air Forced Infusion	- Output: 0.1 micron hydrophobic filtered air - Pressure:150 mmHg or 203 cm H2O maximum air pressure - Flow Rate: Up to 4.8 standard cubic feet per hour (2.25 L/min)	- Output: 0.1 micron hydrophobic filtered air - Pressure:150 mmHg or 203 cm H2O maximum air pressure - Flow Rate: Up to 4.8 standard cubic feet per hour (2.25 L/min)	Same
Illumination	Xenon and Xenon-Mercury lamp with light output form a single port.	Xenon and Xenon-Mercury lamp with light output form a single port.	Same
Laser	Off-the-shelf 2 Watt 532 nm diode-pumped, frequency doubled, solid state laser. Provides visible green (532 nm CW, 2 W max.) class 4 laser for photocoagulation, and a class 2 diode aiming laser (635 nm CW < 1 mW max.).	Off-the-shelf 2 Watt 532 nm diode-pumped, frequency doubled, solid state laser. Provides visible green (532 nm CW, 2 W max.) class 4 laser for photocoagulation, and a class 2 diode aiming laser (635 nm CW < 1 mW max.).	Same
Compressor Module	Electrically powered with a maximum pressure of 42 PSI	Electrically powered with a maximum pressure of 52.5 PSI	Similar, differences not affecting safety and performance
Vacuum Fluidics Module	Anterior module: electrically powered pneumatic actuators for vacuum control Posterior module & 7.5K vacuum fluidics module: electrically powered pneumatic pump for vacuum control	Anterior module: electrically powered pneumatic actuators for vacuum control Posterior module & 12.5K vacuum fluidics module: electrically powered pneumatic pump for vacuum control	Similar, differences not affecting safety and performance

Bi-Blade™+ Vitrectomy Cutter			
Characteristic	**Predicate Device: Bi-Blade™ Vitrectomy Cutter**	**Subject Device: Bi-Blade™+ Vitrectomy Cutter**	**Equivalency Analysis**
Manufacturer	Medical Instrument Development Laboratories, Inc (MidLabs)	Bausch + Lomb	Same

Bi-Blade™+ Vitrectomy Cutter			
Characteristic	**Predicate Device: Bi-Blade™ Vitrectomy Cutter**	**Subject Device: Bi-Blade™+ Vitrectomy Cutter**	**Equivalency Analysis**
US 510(k) Premarket Notification	K153168	K252052	N/A
Product Codes	HQE	HQE	Same
Regulation Number	21 CFR 886.4150	21 CFR 886.4150	Same
Device Class	II	II	Same
Intended Use	Ophthalmic surgery	Ophthalmic surgery	Same
Indications for Use	The UVE and the MID Labs Vitreous Cutter labeled for use with the UVE are used to remove vitreous and intraocular tissue. The UVE can only be used with the MID Labs Vitreous Cutter. The UVE is used in conjunction with ophthalmic surgical equipment as a Host system (typically phacoemulsification or vitreoretinal surgical equipment).	The Bausch + Lomb anterior vitrectomy cutter pouches are indicated for any ocular condition requiring anterior vitrectomy during anterior segment surgery. The Bausch + Lomb posterior vitrectomy cutter pouches are indicated for any vitreoretinal condition requiring vitrectomy during posterior or combined surgery.	Similar, differences not affecting safety and performance
Vitrectomy Cut Rate	Maximum 8,000 cuts per minute (cpm)	Maximum 25,000 cuts per minute (cpm)	Similar, differences not affecting safety and performance
Power source for cutter activation	Pneumatic pressure pulse	Pneumatic pressure pulse	Same
Cutting action format	Guillotine	Guillotine	Same
Cutter return mechanism	Spring return	Spring return	Same
Cutting port format	Side port, two	Side port, two	Same
Cutter size/gauge	20 gauge or smaller	23, 25, 27 gauge	Similar, differences not affecting safety and performance
Aspiration Channel	Through the cutter tubing cannula	Through the cutter tubing cannula	Same
Patient contact material	Stainless steel	Stainless steel	Same
Sterile product packaging and sterility method	Packaged in double Tyvek pouch, sterilized by gamma radiation	Packaged in double Tyvek pouch, sterilized by gamma radiation	Same

7 Summary of Nonclinical Tests

Electrical Safety and Electromagnetic Compatibility (EMC)

Safety tests of the Stellaris Elite™ vision enhancement system have demonstrated its compliance with applicable requirements of the following electrical standards:

- IEC 60601-1:2005+AM1(2012)+AM2:2020, Edition 3.2 (Basic Safety)
- IEC 60601-1-2:2020, Edition 4.1(EMI / EMC)

- IEC 60601-4-2, Edition 1.0 (EMI / EMC)
- IEC 60601-1-6:2020, Edition 3.2 (Usability) w/62366 Assessment
- IEC 60601-1-8:2020, Edition 2.2 (Alarms)
- IEC 60601-2-2:2017, Edition 6 (HF Surgical Devices)
- IEC 60601-2-22:2019, Edition 4 (Therapeutic Laser Devices)
- IEC 80601-2-58:2016, Edition 2.1 (Lens & Vitreous Removal Devices)
- IEC 62366-1:2015+AM1:2020, Edition 1.1 (Usability Engineering Assessment)
- IEC 60825-1:2014, Edition 3 (Safety of Laser Products)

Additional testing was performed with accordance to FDA Guidance "Electromagnetic Compatibility (EMC) of Medical Devices." All testing passed.

Biocompatibility Testing
Biocompatibility assessments for the Bi-Blade+ vitrectomy cutters and Stellaris Elite™ procedure packs and pouches, were performed in accordance with the requirements of ISO 10993-1 to evaluate the impact of the patient contacting material. Test results satisfied the acceptance criteria as defined by the associated ISO standard. Testing passed.

Software Verification and Validation
Software changes were verified and validated in accordance with the Bausch + Lomb software quality procedures which comply with IEC 62304:2006+A1:2015 Medical device software – Software life cycle processes. Testing passed.

Cybersecurity
Cybersecurity testing was performed in accordance with FDA Guidance "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions."

Non-Clinical Performance Data
Non-clinical performance testing was performed to establish substantial equivalence between the predicate device and the revisions as identified within this premarket notification for phacoemulsification and vitrectomy procedures. Testing passed.

Animal/Clinical Studies
No Animal or Clinical Study was performed.

8 Conclusion

The subject devices have the same intended use as the predicate devices and similar technological characteristics. The differences in technological characteristics do not raise new or different questions of safety and performance. Based on the results of the risk assessment and all applicable testing, the subject devices are determined to perform as intended during normal intended use for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy. Therefore, the subject devices meet all applicable requirements for substantial equivalence when compared to the predicate devices.