February 26, 2024

Bausch + Lomb
Ken Nehmer
Director, Regulatory Affairs
3365 Tree Court Industrial Blvd.
St. Louis, Missouri 63122

Re: K232084
Trade/Device Name: Stellaris Elite™ vision enhancement system
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC, HQE, HQF
Dated: January 26, 2024
Received: January 29, 2024

Dear Ken Nehmer:

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K232084

Device Name
Bausch + Lomb Stellaris Elite™ vision enhancement system

Indications for Use *(Describe)*
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.

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 8. 510(K) SUMMARY

## 8.1 General Information

| Submitter: | Contact Person: |
|---|---|
| Bausch + Lomb Inc.<br>3365 Tree Court Industrial Blvd.<br>St. Louis MO 63122<br>General Telephone: 636-226-3017 | Ken Nehmer<br>3365 Tree Court Industrial Blvd.<br>St. Louis MO 63122<br>Telephone: 415-297-0408<br>ken.nehmer@bausch.com |

Preparation Date: February 26, 2024

## 8.2 Names

| | |
|---|---|
| Device Name: | Stellaris Elite™ vision enhancement system |
| 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 |

## 8.3 Predicate Device

K170052 – Stellaris Elite™ vision enhancement system, Bausch + Lomb

## 8.4 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 and vitreous aspirating and cutting as well as endoillumination. Additionally, the Stellaris Elite™ vision enhancement system may be configured with a 532 nm laser module for photocoagulation.
The Stellaris Elite™ vision enhancement system was initially cleared under K162342 which included the introduction of an Adaptive Fluidics feature as well as increase in vitrectomy cut rate. The Vitesse vitrectomy handpiece was introduced and cleared for use on the Stellaris Elite™ vision enhancement system under K170052.

A selection of disposable single-use procedure packs is available for use with this system. These packs contain the necessary tubing to facilitate delivery and removal of air

and fluids to/from the patient as well as a selection of components (cannulas, cutters, probes, 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. Additional Stellaris Elite™ vision enhancement system procedure packs have been made available and these packs contain components that have been used in previously available procedure packs. Some of these Stellaris Elite™ vision enhancement system procedure packs now include the BiBlade vitrectomy cutter produced by Medical Instruments Development Lab (separately cleared via K153168).

The previously cleared Stellaris Elite™ vision enhancement system introduced new feature sets that are not available on the legacy Stellaris/Stellaris PC systems previously cleared under K133242/K133486 respectively. A summary of these additional feature sets for the Stellaris Elite™ vision enhancement system are listed in Table 8-1. The various available system configurations allow for system feature flexibility and are made available for physician convenience.

The most recent clearance to the Stellaris Elite™ vision enhancement system introduced the Vitesse vitrectomy feature and was cleared via K170052 on April 19, 2017.

This traditional 510(k) incorporates updates to User Interface Computer System on Module (SOM) with an introduction of a new replacement Congatec SOM. In addition, the Stellaris Software platform is updated to Windows 10, since the current Stellaris software platform Windows XP is obsolete/incompatible with the new Congatec SOM.

The features remain the same as the previously approved Stellaris Elite™ vision enhancement system. The configuration matrix is listed in Table 8-1. The various available system configurations allow for system feature flexibility and are made available for physician convenience.

**Table 8-1: Stellaris Elite™ vision enhancement system Configuration Table**

| Feature | Configuration by SKU | | |
|---|---|---|---|
| | BL11145 | BL14455 | BL15455 |
| 2500 cpm vitrectomy<br>Initially cleared via K162342 – no substantial changes to the feature since initial clearance | Available | Not Available | Not Available |
| 7500 cpm vitrectomy<br>Initially cleared via K162342 – no substantial changes to the feature since initial clearance | Not Available | Available | Available |
| Vitesse vitrectomy<br>Initially cleared via K170052 | Not Available | Available | Available |
| Adaptive Fluidics<br>Initially cleared via K162342 for use in the anterior segment of the eye | Available | Available | Available |
| Laser module<br>Initially cleared via K133486 – no substantial changes to the feature since initial clearance | Not Available | Not Available | Available |

Abbreviations: cpm = cuts per minute
BL11145: formerly the Stellaris Anterior Vision Enhancement System
BL14455: formerly the Stellaris PC Vision Enhancement System
BL15455: formerly the Stellaris PC Vision Enhancement System with laser

The Stellaris Elite™ vision enhancement system is composed of the following:

| Module/Assembly | Description |
|---|---|
| Electromechanical Base (EMB) | The EMB is intended to act as the central frame including the outer skin through which all system modules attach or receive power. The EMB also serves as the attachment point for all external electrical cords and fluid lines. |
| Computer Unit | Consists of a standard personal computer (PC) customized to include the computer user interface with the Stellaris Elite vision enhancement system. |
| User Interface Module | Provides user control of operation of the Stellaris Elite vision enhancement system. It provides a touch screen display with user input controls to command the system into its various modes and controls activation of functions within each mode. |

| | |
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| Power Supply Module | Provides electrical power to all parts of the Stellaris Elite vision enhancement system integral to the EMB. |
| Device Relationship Management (DRM) | Designed to interact with an external management system to monitor specific activities of the Stellaris Elite vision enhancement system and to provide Bausch + Lomb with a tool to monitor certain system metadata (no patient identifiable data is collected) |
| Anterior Module (Phaco) | The Anterior Module contains all anterior segment connections, circuits, and operating hardware and firmware necessary for anterior segment procedures. It enables ultrasound for continuous, burst, and modulated modes, bimanual phacoemulsification, and bipolar coagulation capability. |
| Posterior Illumination Module<br>(Configurations BL14455 and BL15455 only) | The Stellaris Elite vision enhancement system Illumination Module has two light outputs from two separate light bulbs. The module is designed to support the use of Xenon or Mercury light bulbs. One of the light outputs has a built-in switchable filter to produce tinted Green, Amber or Yellow lights. Lights are transmitted through fiber optics of varying gauge sizes. |
| Compressor Module | The Compressor Module provides the necessary pressure to drive the 2 fluidics modes available for operation of the system vacuum pumps and accessories that require external assistance as drivers for fluid delivery and exchange. This module is the source of bottle infusion and also provides Adaptive Fluidics functionality. It provides pressure to vitrectomy and pinch valves. |
| Fluidics Module | This module is designed for use with anterior and posterior surgical procedures. The module provides vacuum control. The vacuum control is done by the software via a transducer located inside the Fluidics Module. The Fluidics Module provides the electronics, pneumatic actuators, and mechanisms necessary to interface and control the fluidics of the cartridge. The Fluidics Module also monitors the fluid level. A pneumatic vitrectomy cutter control and interface is included. |

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| Automated IV Pole | The unit contains electrical sensors to place the pole at pre-ordained positions via screen generated touch control commands for height requirements in delivery of fluids at certain pressures. |
| Surgical Instrument Tray | The tray is ergonomically located within the base unit and set at a height useful to the surgeon and the assistant. The tray is capable of tilting, and is removable for autoclave sterilization. The tray accommodates a surgical drape. The tray is retractable within the unit when not in use. |
| Foot Controller | The foot controller allows the user to control various features of the system. |
| Remote Control | The remote control unit mimics the GUI functions. The device can control operation of IV pole height, vacuum pressure, ultrasound power, and bipolar power. |
| Digital Media System (option) | Provides a microscope overlay capability. The DMS is used to overlay the surgical parameters output from the Stellaris Elite to the video image of the surgical site captured by the operating microscope camera. The combined image is output to a video monitor and/or a video recorder. |
| Phaco Handpiece | Electrically powered hand-held instrument for anterior segment surgery. There are three capabilities: Generation of ultrasonic energy for disruption of lens tissue; provision for an aspiration path for disrupted tissue from the eye, and the delivery of saline irrigation fluid to the eye for standard, burst, or pulsed phacoemulsification. A phacofragmentation (posterior) handpiece is also available and has two functions: generation of ultrasonic energy for disruption of lens tissue and aspiration path for disrupted tissue from the eye for standard, burst, or pulsed phacofragmentation. |
| Laser Module (Configuration BL15455 only) | The laser module uses an off the shelf 2 Watt 532 nm diode pumped frequency doubled solid state laser coupled coaxially with an off the shelf diode sourced 0.8 mW 635 nm red aiming beam. These are enclosed in a separate box located inside the system. The laser module |

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| | can be driven in either single shot, continuous or pulsed mode. The user may control treatment power, duty cycle, repetition rate, and aiming beam power. |

## 8.5 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.

## 8.6 Summary of Technological Characteristics

The technological characteristics of the Stellaris Elite™ vision enhancement system are substantially equivalent to those of the predicate devices.

| **Characteristic** | **Subject Device:**<br>**Stellaris Elite™ vision enhancement system** | **K170052**<br>**Stellaris PC Vision Enhancement System** |
|---|---|---|
| Intended Use | Anterior/Posterior ophthalmic surgery | Same as subject device |

| | | |
|---|---|---|
| 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 PC 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.<br>The laser modes are intended for retinal photocoagulation and laser trabeculoplasty. |
| Laser capabilities | Yes | Same as subject device |
| User interface | LCD touch screen | Same as subject device |
| Footswitch | Yes | Same as subject device |
| Electrical Characteristics | 90 – 130 VAC, 50/60 Hz<br>200 – 240 VAC, 50/60 Hz | Same as subject device |
| User Interface SOM (System on Module) | Congatec | Kontron |
| Operating System | Windows 10 | Windows XP |
| Maximum vacuum | 660 mmHg* | 600 mmHg |
| eyeTELLIGENCE | Available* | Available |

| | | |
|---|---|---|
| Vitesse revisions including:<br>a. Introduction of Vitesse procedure pack BL5631TD<br>b. Vitesse handpiece manufacturing process revisions<br>c. Firmware update to introduce Vitesse auto tune | Available* | Available |

* incremental improvements introduced since the predicate of K170052

**Performance Data**

**Biocompatibility testing**

Biocompatibility assessment is not required to support the premarket notification. The Stellaris Elite™ vision enhancement systems do not contain direct or indirect patient contacting materials.

**Electrical safety and electromagnetic compatibility (EMC)**

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

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| IEC 60601-1:2020 | Medical electrical equipment - Part 1: General requirements for basic safety and essential performance |
| IEC 60601-1-2:2020 | Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests |
| IEC 60601-1-6:2020 | Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability |
| IEC 60601-2-2:2017 | Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories |

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|---|---|
| IEC 60601-2-22:2019 | Medical electrical equipment - Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment |
| IEC 80601-2-58:2016 | Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery |

Details of the electromagnetic compatibility and safety standard testing can be found in Section 17.

**Software Verification and Validation Testing**

Functional, simulated use, environmental and transport testing were also performed on representative units. Software changes were verified and validated in accordance with the Bausch + Lomb software quality procedures which comply with EN ISO IEC 62304:2006 Medical device software -- Software life cycle processes. Refer to Section 16 for additional details on the specifications and reports.

The Stellaris Elite™ vision enhancement system passed all of the above referenced testing. This testing demonstrates that the functional requirements have been met and that the modified device is substantially equivalent to the predicate devices.

**Mechanical and acoustic testing**

There was no mechanical or acoustical testing performed to support substantial equivalence of this premarket notification.

**Animal Study**

There was no animal study performed to support substantial equivalence of this premarket notification.

**Non-Clinical Performance Data**

Non-clinical performance testing was conducted to establish substantial equivalence between the predicate device and the revisions as identified within this premarket notification.

**Clinical Studies**

There was no clinical study performed to support substantial equivalence of this premarket notification.

## 8.7 Conclusion

The Stellaris Elite™ vision enhancement system shares the same indications for use, design features, and functional features with, and thus is substantially equivalent to, the predicate devices. Non-clinical test results demonstrate that the Stellaris Elite™ vision enhancement system is substantially equivalent to the predicate devices and no new issues of safety or effectiveness have been raised.