DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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April 19, 2017

Bausch + Lomb
Mr. Dan Regan
Director, Regulatory Affairs
3365 Tree Ct. Industrial Blvd
St. Louis, MO 63122

Re: K170052
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: March 27, 2017
Received: March 28, 2017

Dear Mr. Dan Regan:

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,

Denise L. Hampton -S

Malvina 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K170052

Device Name
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 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.

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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	Dan Regan 3845 Corporate Centre Drive O'Fallon, MO 63368 (636) 794-5013 dan.regan@valeant.com

Preparation Date: November 11, 2016

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

3. Predicate Devices

K133486 – Stellaris PC Vision Enhancement System, Bausch + Lomb

K133242 – Stellaris Vision Enhancement System, Bausch + Lomb

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 is a rebranding of the currently cleared Stellaris (K133242) Vision Enhancement System and Stellaris PC (K133486) Vision Enhancement System. The system is based on the technology and the performance of the

existing Stellaris and Stellaris PC Vision Enhancement Systems, and this traditional 510(k) incorporates software and hardware revisions to support the introduction of the new Vitesse vitrectomy feature (including 2 new Vitesse handpieces and supporting accessories). The new Vitesse vitrectomy feature is available on the Stellaris Elite Vision Enhancement System based on the configuration matrix listed in Table 1. The various available system configurations allow for system feature flexibility and are made available for physician convenience.

Table 1: Stellaris Elite Vision Enhancement System Configuration Table

Feature	Configuration by SKU		
	BL11145	**BL14455**	**BL15455**
Adaptive Fluidics Feature cleared under K162342	Available	Available	Available
2500 cpm vitrectomy Feature cleared under K162342	Available	--	--
7500 cpm vitrectomy Feature cleared under K162342	--	Available	Available
Laser module Feature cleared under K133486	--	--	Available
Vitesse vitrectomy *[new feature]*	--	Available	Available

Abbreviations: cpm = cuts per minute
--: Not available
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

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 Stellaris Elite Vision Enhancement System configured with the laser module is additionally intended for retinal photocoagulation and laser trabeculoplasty.

The above indication is a slightly reworded version of the already cleared indications for the Stellaris (K133242) and Stellaris PC (K133486) Vision Enhancement Systems. The rewording includes language regarding the rebranding of the product to Stellaris Elite Vision Enhancement System as well as clarification in regard to the laser module in the last sentence of the indications for use. The addition of the Vitesse vitrectomy feature did not further change the above indication for use statement.

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: Stellaris Elite Vision Enhancement System	K133486 Stellaris PC Vision Enhancement System	K133242 Stellaris Vision Enhancement System
Intended Use	Anterior/Posterior ophthalmic surgery	Same as subject device	Use in ophthalmic procedures
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 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. The laser modes are intended for retinal photocoagulation and laser trabeculoplasty.	The Bausch + Lomb Stellaris Vision Enhancement System device 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, irrigation/aspiration, bipolar, coaxial, and bipolar coagulation, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. Use only Bausch + Lomb disposable packs and handpieces designated for use with the system.
Laser capabilities	Yes	Same as subject device	No
User interface	LCD touch screen	Same as subject device	Same as subject device
Footswitch	Yes	Same as subject device	Same as subject device
Electrical Characteristics	90 – 130 VAC, 50/60 Hz 200 – 240 VAC, 50/60 Hz	Same as subject device	Same as subject device

7. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Stellaris Elite Vision Enhancement System is substantially equivalent to the predicate devices and is safe and effective for the emulsification and removal of cataracts, anterior and posterior segment vitrectomy.

8. Brief Summary of Nonclinical Tests

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 + C1(2006) + C2(2007) + AM1(2012) or IEC 60601-1:2012	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 ed3.0 (2007)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
IEC 60601-1-6:2010	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard: Usability
IEC 60601-2-2:2009	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
IEC 60601-2-22:2007	Medical electrical equipment - Part 2-22: Particular requirements for the safety of diagnostic and therapeutic laser equipment
IEC 80601-2-58:2008	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

Substantial equivalence is supported the successful tests for functional, simulated use, environmental and transport testing 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.

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 equivalent to the predicate devices.

9. 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.