March 24, 2017

Bausch + Lomb Inc.
Mr. Ken Nehmer
Senior Manager, Regulatory Affairs
3365 Tree Ct. Industrial Blvd.
St. Louis, MO 63122

Re: K162342
Trade/Device Name: Stellaris Elite Vision Enhancement System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacoemulsification system
Regulatory Class: Class II
Product Code: HQC, HQE, HQF
Dated: March 17, 2017
Received: March 20, 2017

Dear Mr. 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 (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](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](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](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

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
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.

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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1. General Information

| Submitter: | Bausch + Lomb Inc.  
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|            | St. Louis MO 63122  
|            | General Telephone: 636-226-3017  
| Contact Person: | Ken Nehmer  
|            | 351 Buena Vista Avenue E.  
|            | Unit 501E  
|            | San Francisco, CA 94117  
|            | 415-297-0408 (Cell)  
| ken.nehmer@bausch.com |

Preparation Date: August 19, 2016

2. Names

Device Name(s): Stellaris Elite Vision Enhancement System
Classification Name(s): Phacofragmentation Unit, Vitreous Aspiration and Cutting Instrument
Common Name: Ophthalmic surgical system for cataract and vitreo-retinal surgery
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 system is based on the technology and the performance of the existing Stellaris and Stellaris PC Vision Enhancement Systems. This traditional 510(k) incorporates software and hardware revisions to support the introduction of new features including Adaptive Fluidics, high speed vitrectomy, and supporting accessories. The Stellaris Elite Vision Enhancement System is available in various configurations.

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.
6. Summary of Technological Characteristics

The technological characteristics of the Stellaris Elite Vision Enhancement System are substantially equivalent to those of the predicate devices.

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<tbody>
<tr>
<td>Intended Use</td>
<td>Anterior/Posterior ophthalmic surgery</td>
<td>Same as subject device</td>
<td>Use in ophthalmic procedures</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>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.</td>
<td>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.</td>
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<tr>
<td>Laser capabilities</td>
<td>Yes</td>
<td>Same as subject device</td>
<td>No</td>
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<tr>
<td>User interface</td>
<td>LCD touch screen</td>
<td>Same as subject device</td>
<td>Same as subject device</td>
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<tr>
<td>Footswitch</td>
<td>Yes</td>
<td>Same as subject device</td>
<td>Same as subject device</td>
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<tr>
<td>Electrical Characteristics</td>
<td>90 – 130 VAC, 50/60 Hz</td>
<td>Same as subject device</td>
<td>Same as subject device</td>
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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 as safe and effective as the predicate 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 60601-1-2 ed3.0 (2007)
- IEC 60601-1-6:2010
- IEC 60601-2-2:2009

Substantial equivalence is supported by successful test results for functional, simulated use, biocompatibility, shelf life, 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 applicable standards and functional testing. This testing demonstrates that the functional requirements have been met and that the modified device is substantially 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.