MAR 1 2 2014

510(k): K133486

BAUSCH + LOMB

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Section 8 –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	Timothy W Capehart 636-226-3017 (Office) 636-226-3245 (Fax) Timothy.Capehart@bausch.com

Preparation Date: November 6, 2013

2. Names

Device Name(s): Stellaris®*PC* Vision Enhancement System

Classification Name(s): 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

- K101325 – Stellaris®PC Vision Enhancement System, Bausch & Lomb
- K022760 – Millenium Microsurgical System, Bausch & Lomb
- K071687 - Family of IRIDEX IQ Laser Systems (1Q532, 1Q577, IQ 630-670, 1Q8 10) & Delivery Device Accessories

4. Product Description

The Bausch + Lomb Stellaris®PC Vision Enhancement System is 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, this model includes an optional 532nm laser module for photocoagulation.

The system is based on the technology and the performance of the existing Stellaris®PC Vision Enhancement System, and this traditional 510(k) incorporates software revisions, a hardware revision to the power supply, and the additional of an optional laser photocoagulation module.

The system enhances the ability to perform as one combined anterior and posterior system for increased efficiency.

5. Indications for Use

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 trabeculaplasty.

6. Summary of Technological Characteristics

The technological characteristics of the Stellaris®PC Vision Enhancement System are substantially equivalent to those of the predicate device.

Characteristic	**Subject Device** Stellaris®PC Vision Enhancement System	**K101325** Stellaris®PC Vision Enhancement System	**K022760** Millennium Laser Photocoagulator System	**K071687** **Iridex IQ Laser Family**
Intended Use	Anterior/Posterior ophthalmic surgery	Anterior/Posterior ophthalmic surgery	Intended for use in ophthalmic procedures	Intended for use in ophthalmic and dermatologic al procedures
Indications for Use	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 trabeculaplasty.	The Bausch & LombTM Stellaris® PC 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 phacofragmentation (coaxial or bimanual), irrigation/aspiration, bipolar diathermy, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. Uses only Bausch & Lomb disposable packs and handpieces designated for use with the system-	The laser modes are intended for retinal photocoagulation and laser trabeculaplasty. Delivery devices available are the Endoprobe for intraocular endolaser surgery, and the Laser Indirect Ophthalmoscope Plus (LIO+) for transpupillary laser delivery for patients in the supine position.	(Ophthalmic 532nm only) Indicated for retinal photocoagula tion, laser trabeculoplast y, iridotomy, iridoplasty including: · Retinal photocoagula tion (RPC) for the treatment of > Diabetic retinopathy, including: - Nonproliferat ive retinopathy - Macular edema -Proliferative retinopathy > Retinal tears and detachments > Lattice degeneration > Age-related macular degeneration (AMD) > Retinopathy of

Characteristic	**Subject Device** Stellaris®PC Vision Enhancement System	**K101325** Stellaris®PC Vision Enhancement System	**K022760** Millennium Laser Photocoagulator System	**K071687** **Iridex IQ Laser Family**
				prematurity > Sub-retinal (choroidal) neovascularization > Central and branch retinal vein occlusion · Laser trabeculoplasty, iridotomy, iridoplasty for the treatment of glaucoma, including > Primary open angle/Closed angle
Laser capabilities	Yes	No	Yes	Yes
User interface	LCD touch screen	LCD touch screen	NA	LCD touchscreen
Footswitch	Yes	Yes	Yes	Yes
Electrical Characteristics	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz	90-130 VAC, 50/60 Hz 200-240 VAC, 50/60 Hz

7. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Stellaris®PC 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 and Results

Safety tests of the Stellaris®PC 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)	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
or IEC 60601-1:2012	
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
IEC 60601-1-6:2010	Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance. Collateral standard. Usability
IEC 62366:2007	Medical devices - Application of usability engineering to medical devices
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 60825-1:2007	Safety of laser products - Part 1: Equipment classification and requirements

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.

The Stellaris®PC Vision Enhancement System passed all of the above tests with no exceptions. This testing demonstrates that the functional requirements have been met and that the modified device is equivalent to the predicate device.

9. Conclusion

The Stellaris®PC Vision Enhancement System shares identical indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 12, 2014

Bausch + Lomb, Inc.
% Mr. Timothy W. Capehart
Manger Regulatory Affairs, Equipment and Instruments
3365 Tree Court Industrial Boulevard
Saint Louis, MO 63122

Re: K133486
Trade/Device Name: Stellaris PC Vision Enhancement System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system.
Regulatory Class: Class II
Product Code: HQC, HQE, HQF
Dated: February 5, 2014
Received: February 7, 2014

Dear Mr. Capehart:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Kesia Y. Alexander -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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K133486

Device Name
Stellaris®PC Vision Enhancement System

Indications for Use *(Describe)*

The Bausch & Lomb StellarisPC 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 trabeculaplasty.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Rahul K. Ram -S (Affiliate)
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