510(k): K101325

Bausch & Lomb

510(k) Summary Statement
Bausch & Lomb Stellaris PC Vision Enhancement System

AUG 17 2010

July 26,2010

Applicant's Name and Address

Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609

Contact Person

Ned Luce
Director, Global Regulatory Affairs
Bausch & Lomb, Inc.
1400 North Goodman Street
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1. Identification of device

Common Name:	ophthalmic surgical system for cataract and vitreo-retinal surgery
Trade Name:	Bausch & Lomb™ Stellaris PC Vision Enhancement System
Classification:	Class II ophthalmic microsurgical system including: -Phacofragmentation system (21 CFR 886.4670 -Vitreous Aspirating and Cutting Device (21 CFR 886.4150
Device classification:	Class II (21 CFR 886.4670 and 21 CFR 886.4150)
Pro Code:	HQC, HQE

2. Description of device

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.

The Stellaris® PC™ Vision Enhancement system is the next generation Stellaris® NGX Microsurgical System. The new system is based on the technology and the performance platform of the existing Stellaris® NGX Microsurgical System and is designed to improve surgical efficiency, surgeon ergonomics, control of fluidics and aesthetics.

The system incorporates vacuum based fluidics to meet the needs of anterior and posterior procedures. The system enhances the ability to perform as one combined anterior and posterior system for increased efficiency. The ultrasound lens removal system extends and improves upon existing technologies with new and improved designs in the phaco hand-piece.

3. Intended use

The Bausch & Lomb™ 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 phacoemulsification (coaxial or bimanual), irrigation/aspiration, bipolar diathermy, vitrectomy, viscous fluid injection/removal and air/fluid exchange operations. Use only Bausch & Lomb™ disposable packs and handpieces designated for use with the system.

4. Substantial Equivalence

510(k)	Clearance Date	Device Description
K063331	12/14/2006	Bausch & Lomb™ Stellaris® NGX Microsurgical System
K961310	6/27/1996	Bausch & Lomb™ Premiere II Millennium® Microsurgical System
K082473	1/9/2009	Bausch & Lomb™ Stellaris® NGX System

5. Technological Characteristics

The Bausch & Lomb™ Stellaris® PC™ Vision Enhancement System utilizes similar technology as the Stellaris® NGX Microsurgical System with similar ergonomic, aesthetics, and reliability upgrades. The base unit contains all of the modules, however, the module area is not visible to the user. The fluidics systems for the Stellaris® PC Vision Enhancement System are comprised of similar vacuum technology as the Premiere II Millennium® Microsurgical System. New modules for the Stellaris® PC™ Vision Enhancement System have been added or enhanced to provide posterior surgical functionalities such as endoillumination, viscous fluid injection/extraction, fluid/air exchange and high speed vitrectomy..

6. Perfomance Data:

The Stellaris® PC™ Vision Enhancement System will be manufactured in compliance with FDA and ISO quality systems and device related international, domestic, and industry standards and requirements. System verification and validations have demonstrated that the functional requirements and system specifications have been met and are currently ready for commercial release and distribution. This submission contains all testing data and validation summaries supporting system function.

Non Clinical Testing for Performance Data (Standards Based)

#	Document Title	Version	Date
1.	IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety; (Amd.1-1991) (CENELEC EN 60601-1:1990) (Amd. 2-1995(Corrigendum-1995) – Also includes requirements for enclosures covered in IEC 60529	Ed:2	1998/12/01
2.	UL 60601-1 UL Standard for Safety Medical Electrical Equipment Part 1: General Requirements for Safety; Includes CSA C22.2 N0. 601.1	Edition 1	2003/04/25
3.	IEC 60601-1-1:2000 Medical Electrical Equipment Part 1: General Requirements for Safety – Collateral Standard: Safety requirements for medical electrical systems	–	2000/12/01

#	Document Title	Version	Date
4.	EN60601-1-2:2001 Medical Electrical Equipment Part 1: General Requirements for Safety 2. Collateral Standard: Electromagnetic Compatibility - Requirements and tests, including Amendment A1:2006	-	2004/11/01
5.	IEC 60601-2-2 Medical Electrical Equipment Part 2-2: Particular requirements for the safety of high frequency surgical equipment	-	2006/0701
6.	FCC Part 15 Part B and Part C Radio Frequency Devices	–	Nov 5, 2004
7.	FCC Supplement C Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields	01-01	June 29, 2001
8.	FCC OET Bulletin 65 Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields	97-01	Aug 1997
9.	EN 300 328 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive	1.5.1	2004-08
10.	EN 300 328-1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Part 1: Technical characteristics and test conditions	1.3.1	2001-12
11.	EN 300 328-2 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband Transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using spread spectrum modulation techniques; Part 2: Harmonized EN covering essential requirements under article 3.2 of the R&TTE Directive	1.2.1	2001-12
12.	ARIB STD-T66 (Japan) Radio Equipment for Second-generation Low-power Data Communications Systems Radio Stations" and "Wireless LAN Systems' Equipment	2.1	March 2003

#	Document Title	Version	Date
13.	ISO 15004-2:2007 Ophthalmic Instruments Fundamental Requirements and Test Methods Part 2: Light Hazard Protection	2	12/17/2007
	Transportation Standards		
#	**Document Title**	**Version**	**Date**
14.	ISTA Schedule 3H "Products or Packaged-Products in Mechanically Handled Bulk Transport Containers" for the completed system	2005	6/2005
15.	Service Modules: ISTA Project 3A, "Packaged-Products for Parcel Delivery System Shipment, 150lbs. or Less (standard, small, flat or elongated)"	2006	5/2006
16.	Disposable Packs: ASTM D4169 Standard Practice for Performance Testing of Shipping Containers and Systems	Ed:08	08/01/2008

Biocompatibility Standards			
#	**Document Title**	**Version**	**Date**
17.	ISO 10993:2003 Biological Evaluation of Medical Devices- Evaluation and Testing	2003	09/08/2009
18.	ISO 10993-5:2009 Biological Evaluation of Medical Devices- Tests for in-vitro cytotoxicity	2009	09/08/2009
19.	ISO 10993-10:2002 Biological Evaluation of Medical Devices- Tests for Irritation and Delayed Type hypersensitivity	2002	09/08/2009

7. Packaging

The Bausch &Lomb™ Stellaris® PC™ Vision Enhancement System is housed in a dedicated single free standing unit in which all major components are enclosed as an integrated system. Sterile accessory surgical packs are packaged separately in sealed Tyvek packaging.

8. Clinical data:

The Bausch &Lomb™ Stellaris® PC™ Vision Enhancement System is the next generation of the Stellaris® NGX Microsurgical System and as such provides for procedures and use of tools that have extensive clinical and surgical use. Modules for posterior surgical procedures have predicates from the Bausch & Lomb™ Premiere II® Millennium Microsurgical System with modifications and upgrades. Clinical investigations were deemed not necessary for the planned marketing of this system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Bausch & Lomb, Inc.
c/o Mr. Daniel W. Lehtonen
Senior Staff Engineer
Intertek Testing Services NA, Inc.
2307 E. Aurora Rd, Unit B7
Twinsburg, OH 44087

AUG 17 2010

Re: K101325
Trade/Device Name: Stellaris PC Vision Enhancement System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: II
Product Codes: HQC, HQE
Dated: July 30, 2010
Received: August 2, 2010

Dear Mr. Lehtonen:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Alexander

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K101325

SECTION 4 : INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K101325

Device Name: Bausch & Lomb™ Stellaris PC Vision Enhancement System

Indication for Use

The Bausch & Lomb™ 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.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the –counter-use _____

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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