K082473

Bausch & Lomb

JAN - 5 2009

510(k) Summary Statement
Bausch & Lomb Stellaris Microsurgical System
(Pressurized Infusion Pump)

Applicant's Name and Address

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

Contact Person

Ned L. Luce
Director, Global Regulatory Affairs
Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609
(585) 338-6368

1. Identification of device

Common Name:	ophthalmic surgical system for cataract and vitreo-retinal surgery
Trade Name:	Bausch & Lomb™ Stellaris Microsurgical 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 Microsurgical System is an integrated ophthalmic microsurgical system designed for use in anterior and posterior segment surgery including phacofragmentation and vitreous aspirating and cutting- anterior vitrectomy.

The Stellaris system is a next generation system based on the Millennium phacoemulsification system, and has been cleared under K063331 for anterior segment procedures including anterior vitreous (posterior). The modification to the current Stellaris system is to provide a pressurized infusion pump system for the bottle assembly which was heretofore placed on the IV pole. The IV pole requires a power generated action to raise and lower the pole to gain appropriate pressure for the delivery of BSS saline during intraocular surgery. The pressurized infusion system alleviates this necessity by allowing the IV pole to remain stationary. A bottle hangar assembly is attached to the IV pole in a stationary position to allow delivery of fluids from the fluid bottle at the appropriate and desired pressure controlled by the pressurized infusion system embedded in the base unit during the intraocular surgery procedure. The infusion pump mechanism is already an integral part of the Stellaris system that has not been activated previously.

The current Stellaris system incorporates both vacuum and flow-based fluidics system (peristaltic pump) to meet current and future needs of anterior and posterior procedures. The compressor module of the Stellaris unit provides the mechanical and pneumatic interfaces to the pressurized infusion system.

3. Intended use

The Bausch & Lomb™ Stellaris Microsurgical 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.

4. Substantial Equivalence

510(k)	Clearance Date	Device Description
K063331	12/19/2006	Bausch & Lomb NGX Microsurgical System (Stellaris)
K961310	6/27/1996	Bausch & Lomb Premiere II Millennium Microsurgical System

5. Technological Characteristics

The B&L Stellaris™ Microsurgical System utilizes the same technology as the Millennium™ System but with ergonomic, aesthetics, and reliability upgrades to the phaco hand-piece and system. The base unit contains all of the modules, however, the module area is not visible to the user. The fluidics systems for the Stellaris System are comprised of the same technology as the Millennium but have been upgraded for reliability and manufacturability. The pressurized infusion assembly of the Stellaris Microsurgical System is an integral part of the system however has not been active until now. The purpose of the pressurized infusion system serves to provide appropriate pressure on demand to the accessory fluid bottle(s) which are placed onto the IV pole hangar assembly, and allows for the IV pole to be in a stationary position while providing the desired amount of pressure to the bottle by activation from the surgeon.

6. Perfomance Data:

The Stellaris 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 validation will demonstrate that the functional requirements and system specifications will have been met prior to commercial release and distribution.

7. Packaging

The B&L Stellaris Microsurgical 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 pouches.

8. Clinical data:

The B&L Stellaris Microsurgical System is the next generation of the Millennium Microsurgical System and as such provides for procedures and use of tools that have extensive clinical and surgical use. Clinical investigations were deemed as not necessary for the planned marketing of this system.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bausch & Lomb, Inc.
c/o Ned L. Luce
Director, Global Regulatory Affairs
1400 North Goodman Street
Rochester, NY, 14609

JAN - 5 2009

Re: K082473
Trade/Device Name: Stellaris Microsurgical System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC, HQE
Dated: December 16, 2008
Received: December 18, 2008

Dear Mr. Luce:

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.

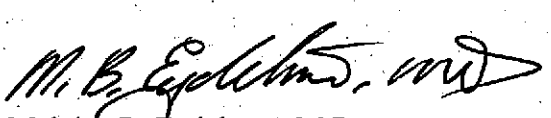
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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 STATEMENT

510(k) Number (if known): K082473

Device Name: Bausch & Lomb™ NGX Microsurgical System

Indication for Use

The Bausch & Lomb™ NGX Microsurgical 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.

(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_____

510(k) Number K082473

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

510(k) Number K082473