K063331

Bausch & Lomb

510(k) Summary Statement
Bausch & Lomb NGX Microsurgical System

DEC 19 2006

Applicant's Name and Address

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

Contact Person

Lisa Graney
Manager,Global Regulatory Affairs
Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609
(585) 338-6612

1. Identification of device

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

The NGX system is the next generation Millennium phacoemulsification system. The new system is based on the technology and the performance of the existing Millennium system and is designed to improve surgical efficiency, surgeon ergonomics, more reliable control of fluidics, which will help IOP control, better data collection capability, and improved aesthetics.

The system incorporates both vacuum and flow-based fluidics system (peristaltic pump) to meet current and future needs of anterior and posterior procedures. This enhances the ability to perform as one combined 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™ 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.

4. Substantial Equivalence

510(k)	Clearance Date	Device Description
K961310	6/27/1996	Bausch & Lomb Premiere II Millennium Microsurgical System
K060366	4/7/2006	AMO Ophthalmic Surgical System
K952213	8/9/1995	Alcon 2000 Legacy Microsurgical System
K021566	7/2/2002	Alcon Infiniti Microsurgical System

5. Technological Characteristics

The B&L NGX 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 NGX System are comprised of the same technology as the Millennium but have been upgraded for reliability and manufacturability.

6. Perfomance Data:

The NGX 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.

Non Clinical Testing for Performance Data (Standards Based)

Document Title	Version	Date
IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Safety, including Amendments A1:1993, A11:1993, A12:1993, A2:1995 and A13:1996	Second Edition	October 1997
IEC 60601-1-1:2000 Medical Electrical Equipment Part 1: General Requirements for Safety- Collateral Standard: Safety requirements for medical electrical systems	–	December 2000
IEC 60601-1-2:2000 Medical Electrical Equipment Part 1-2: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility - Requirements and tests	Edition 2.1	November 2004

Document Title	Version	Date
IEC 60601-2-2 :1998 Medical Electrical Equipment Part 2-2: Particular requirements for the safety of high frequency surgical equipment	–	September 1998
IEC 61847 Ultrasonics – Surgical systems – Measurement and declaration of the basic output characteristics	First edition	1998-01
UL-746C UL Standard for Safety Polymeric Materials - Use in Electrical Equipment Evaluations	Sixth Edition	9/10/2004
IEC 60529 Degrees of protection provided by enclosures (IP code)	2.1	2001-02
ASTM F1980-02 Standard Guide for Accelerated Aging of Sterile Medical Device Packages	–	1/10/2002
ASTM D 4169-05 Standard Practice for Performance Testing of Shipping Containers and Systems	–	10/01/2005
EN ISO 10993:2003 Biological Evaluation of Medical Devices - Parts 1, 5, 10, 11	–	08/01/2003
ISO 11737-1:2006 (E) Sterilization of medical devices — Microbiological methods —Part 1: Determination of a population of microorganisms on products	Second Edition	2006-04-01
ISO 11607-1:2003 (E) Packaging for terminally sterilized medical devices	Second Edition	02/15/2003
ANSI/AAMI/ISO 11137:1994 Sterilization of Health care Products – Requirements for validation and routine control – Radiation sterilization	–	1994
EN 552:1994 Sterilization of medical devices – Validation and routine control of sterilization by irradiation	–	01/01/1994
EN ISO 17664:2004 Sterilization of medical devices —Information to be provided by the manufacturer for the processing of resterilizable medical devices	First Edition	2004-03-01
ISO/TS 15843 Sterilization of Health care Products – Radiation sterilization – Product families and sampling plans for verification dose experiments and sterilization dose audits, and frequency of sterilization dose audits.	–	02/21/2001
MIL-STD-1472F (IV Pole)	F	August 1999
NAVMAT-P-9492 "Random Vibration"	–	May 1979
MIL-STD-202G, Method 213B, Test Condition C "Mechanical Shock"	G	Feb.8, 2002
MIL-STD-810F, Method 514.4 "Transportation Vibration"	F	Jan 1, 2000
NSTA Schedule 2A	–	
ISTA Project 2A	Version date June, 1999	June 29, 2000
IEC 60601-1-4:1996/A1:1999 Medical Electrical Equipment Part 1: General requirements for safety- 4. Collateral Standard: Programmable electrical medical systems.	Edition 1.1	April 2000
Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices	-	05/11/2005

Document Title	Version	Date
IEEE 1012, Standard for Software Verification and Validation	-	12/08/2004
EN ISO 13485:2003 Medical Devices-Quality Management Systems – Requirements for Regulatory Purposes	–	July 31, 2003
EN 980:2003 Graphical Symbols for Use in the Labeling of Medical Devices	–	April 1, 2003
ISO 15223:2004 Medical devices Symbols to be used with medical device labels, labeling and information to be supplied-First Edition: Amendment 1: 8/01/2002; Amendment 2: 02/15/2004	–	04/15/2000
EN 1041:1998 Information Supplied By The Manufacturer with Medical Devices	–	
IEC 60417 DB Graphical Symbols for Use on Equipment - Part 1: Overview and Application-(DATABASE SNAPSHOTS:07/03/2006)	Third edition	05/21/2006
EN ISO14971:2000/A1:2003 Medical Devices - Application of Risk Management to Medical Devices-ISO 14971:2000 + A1:2003; Amendment A1: March 2003	–	12/01/2000
93/42/EEC, European Union Medical Device Directive	–	July 1993
2002/96/EC European Union Waste Electrical and Electronic Equipment (WEEE)	–	January 2003
2002/95/EC European Union Directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment	–	January 2003

7. Packaging

The B&L NGX 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 NGX 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

Bauch & Lomb, Inc.
c/o Ms. Lisa Graney
1400 North Goodman Street
Rochester, NY 14609

DEC 19 2006

Re: K063331
Trade/Device Name: Bausch & Lomb™ NGX Microsurgical System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: II
Product Code: HQC, HQE
Dated: November 3, 2006
Received: November 6, 2006

Dear Ms. Graney:

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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

SECTION 4 : INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K063331

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 ✓ OR Over-the –counter-use _____

Denise L. McCarthy
(Division Sign-off)
Division of Ophthalmic Devices

510(k) Number K063331