FEB 1 0 2004

K033941

Millennium™ Peristaltic Pump System

510(k) SUMMARY
(per 21 CFR §807.92)

Submitter's Name: **Address:**	Bausch & Lomb 3365 Tree Court Industrial Blvd. St. Louis, MO 63122
Telephone #: **Fax #:**	(636) 226-3183 (636) 226-3245
Official Correspondent:	Dennis Pozzo Regulatory Affairs Specialist
Date Summary Prepared:	February 1, 2004
DEVICE NAME:	Millennium™ Peristaltic Pump System
Classification/Common name:	Phacoemulsification Microsurgical System
Proprietary name:	Millennium™ Peristaltic Pump System
Class:	II
Panel:	Ophthalmic
Product Code:	HQF

The marketed device(s) to which substantial equivalence is claimed:
Millennium™ Microsurgical System

PRODUCT DESCRIPTION:

The Peristaltic Pump System consists of a new module and will fit into the existing base of Millennium Microsurgical Systems. It is an anterior only module designed to be used with phacoemulsification. The module is flow based in that it will provide aspiration by means of a peristaltic pump. A peristaltic pump is a positive displacement type of pump which controls flow rate by the rotational speed of the pump head.

The module will contain an interface for the disposable Peristaltic Pump Cartridge and one pneumatic output. The interface for the peristaltic pump cartridge ensures the peristaltic tubing is properly positioned for engagement by the pump head and the pressure sensor and integral pinch valves are properly aligned. The pneumatic connection delivers air pressure sufficient to drive a vitrectomy cutter.

The Peristaltic Pump Cartridge will be provided as a sterile, single use product. The cartridge consists of a molded housing with pre-connected irrigation tubing which acts as a conduit for instilling balanced salt solution (BSS). The tubing interfaces with the rotating peristaltic roller

pump head. In addition, the cartridge contains a pressure transducer that interfaces with the transducer PCB on the peristaltic module to measure the vacuum within the aspiration path of the cartridge.

STATEMENT OF INDICATIONS FOR USE

Millennium Peristaltic Pump System
The Bausch & Lomb (B&L) Millennium Peristaltic Pump System is intended for the introduction of Balanced Salt Solution (BSS) into the eye, as well as, the aspiration of fluid/tissue from the eye during ophthalmic anterior surgery. The Millennium Peristaltic Pump System consists of the B&L CX4100 module to be used with the B&L Millennium Microsurgical System and the B&L Peristaltic Phaco Pack, CX5310 sterile single-use accessory pack which consists of the various components/accessories necessary to enable the use of B&L Anterior Handpieces with the Millennium Microsurgical System.

SUBSTANTIAL EQUIVALENCE

- **Comparison to Millennium Concentrix Module**

  Similarities

  The Millennium™ Peristaltic Pump Module is substantially equivalent to the Millennium Concentrix Module in that both:

  1) are flow based pumps and
  2) are used in the Millennium Microsurgical System for anterior segment surgeries.

  Differences

  The main difference between the two modules is the pump technology, the concentrix module utilizes a scroll type pump and the peristaltic module utilizes a peristaltic type pump, hence the name.

- **Comparison to Millennium Venturi Module**

  Similarities

  The Millennium™ Peristaltic Pump Module is substantially equivalent to the Millennium Venturi Module in that both:

  1) have an air venting mode and
  2) are used in the Millennium Microsurgical System for anterior segment surgeries.

  Differences

  The main difference between the two modules is the pump technology, the venturi module utilizes a venturi (vacuum based) type pump and the peristaltic module utilizes a peristaltic (flow based) type pump.

- **Comparison to the Alcon Legacy and Allergan Sovereign**

  Similarities

  The Millennium™ Peristaltic Pump Module is substantially equivalent to the Alcon Legacy cleared via the 510(k) process, #K911808 and the Allergan Sovereign cleared via the 510(k) process, #K981116 in that they all utilize a peristaltic pump for anterior ophthalmic procedures.

  Differences

  The main difference between the Millennium Peristaltic Pump Module and the Alcon Legacy and Allergan Sovereign Systems is, the Millennium System is a modular system the Alcon and Allergan Systems are not.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 0 2004

Bausch & Lomb, Inc.
c/o Dennis Pozzo
Regulatory Affairs Specialist
3365 Tree Court Industrial Blvd.
St. Louis, MO 63122

Re: K033941
Trade/Device Name: Millennium™ Peristaltic Pump System
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQF
Dated: December 17, 2003
Received: December 19, 2003

Dear Mr. Pozzo:

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 (301) 594-4613. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K033941

510(K) Number -

Device Name:

Indications for Use:

Millennium Peristaltic Pump System
The Bausch & Lomb (B&L) Millennium Peristaltic Pump System is intended for the introduction of Balanced Salt Solution (BSS) into the eye, as well as, the aspiration of fluid/tissue from the eye during ophthalmic anterior surgery. The Millennium Peristaltic Pump System consists of the B&L CX4100 module to be used with the B&L Millennium Microsurgical System and the B&L Peristaltic Phaco Pack, CX5310 sterile single-use accessory pack which consists of the various components/accessories necessary to enable the use of B&L Anterior Handpieces with the Millennium Microsurgical 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 _____

(Division Sign-Off)

Dennis L. McCarthy
(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number _____

510(k) Number K033941

Bausch & Lomb Inc