DEC 17 2003

K033653

Venturi Phaco Packs

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:	November 13, 2003
Device Name/ Proprietary name:	Venturi Phaco Packs
Classification/Common Name	Phaco Packs
Class:	II
Panel:	Ophthalmic
Product Code:	HQC

The marketed device(s) to which substantial equivalence is claimed: Venturi Phaco Packs

PRODUCT DESCRIPTION:

The Bausch & Lomb (B&L) Phacoemulification Disposable Packs are an accessory to the Millennium, Premiere and Protege Microsurgical Systems for use in performing phacoemulsification procedures. Phacoemulsification involves the ultrasonic disintegration of the opacified crystalline lens (cataract) from the eye. This process is accomplished by means of an electronically driven handpiece which: 1) emulsifies the lens, 2) facilitates the irrigation of the anterior chamber and 3) facilitates the aspiration of the emulsified lens material and irrigant from the eye

Substantial Equivalent Basis

The modified DP4310 and new DP4305 Venturi Phaco Packs are substantially equivalent to the existing DP4310 (K955901) and DP4330 and DP4345 (combination K955901 and K952259). See Comparison Matrix.

Comparison Matrix

Components	Currently Marketed DP4310 Pack	Currently Marketed DP4330 & DP4345 Pack	Proposed DP4310 Pack	Proposed DP4305 Pack
Collection Cassette	X	X	X	X
I/A Tube Set	X	X	X	X
Test Chamber	X (2ea)	X (2ea)	X (1ea)	X (1ea)
Irrigation Sleeve	X (2ea.)	X (2ea.)	X (2ea.)	X (1ea.)
Needle Wrench	X	X	X	X
Filter Irrigation Administration Set	X	X	X	X
Tray Support Cover	X	X	X	
Auxiliary Drape	X	X	X	
Cassette Stopper and Cap	X	X		
Remote Control Drape	X	X	X	
Instructions (Directions for Use)	X	X	X	X
Phaco Needle		X		
2.5mm Slit Knife		X		

Components	Currently Marketed DP4310 Pack	Currently Marketed DP4330 & DP4345 Pack	Proposed DP4310 Pack	Proposed DP4305 Pack
Intended Use	Phaco packs used for anterior segment surgery with Bausch and Lomb Microsurgical Systems, such as the Millennium, Protégé, and Premiere.	Phaco packs used for anterior segment surgery with Bausch and Lomb Microsurgical Systems, such as the Millennium, Protégé, and Premiere.	Phaco packs used for anterior segment surgery with Bausch and Lomb Microsurgical Systems, such as the Millennium, Protégé, and Premiere.	Phaco packs used for anterior segment surgery with Bausch and Lomb Microsurgical Systems, such as the Millennium, Protégé, and Premiere.
Sterilization Method	Gamma	Gamma	Gamma	Gamma
Sterility Assurance Level	10^{-6}	10^{-6}	10^{-6}	10^{-6}
Single Use	Yes	Yes	Yes	Yes

Statement of Indications for Use

The Venturi Phaco Packs are intended for use with a Bausch & Lomb Millennium, Protegé or Premiere microsurgical system for the phacoemulsification of an opacified crystalline lens during anterior segment surgery.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 17 2003

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

Re: K033653
Trade/Device Name: Venturi Phaco Pack
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation system
Regulatory Class: Class II
Product Code: HQC
Dated: November 18, 2003
Received: November 21, 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

510(K) Number – K033653

Device Name: Venturi Phaco Pack

Indications for Use:

The Venturi Phaco Packs are intended for use with a Bausch & Lomb Millennium, Protegé or Premiere microsurgical system for the phacoemulsification of an opacified crystalline lens during anterior segment surgery.

(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) Clay R. Butterman

(Division Sign Off)
Division of Ophthalmic Ear,
Nose and Throat Devices
510(k) Number K033653

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Bausch & Lomb Surgical