K041998

AUG 16 2004

Phaco Chop Needle

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:	May 25, 2004
Device Name/ Proprietary name:	Phaco Chop Needle
Classification/Common Name	Phaco Needles
Class:	II
Panel:	Ophthalmic
Product Code:	HQC

The marketed device(s) to which substantial equivalence is claimed: Bausch & Lomb Phaco Needles

PRODUCT DESCRIPTION:

The phacoemulsification (phaco) needle is the cylindrical, metal tip which is connected to the distal end of a phaco handpiece. The needle is the component of a phaco system which, as driven by the ultrasonic handpiece, contacts and fragments the cataractous crystalline lens. Irrigation fliud flows around the external surface of the needle into the eye. The emulsified lens material and irrigant are aspirated from the eye through the phaco needle lumen. The proposed Phaco Chop Needle has the same external and internal tip design as Bausch & Lomb's currently marketed MicroFlow and MicroFlow Plus Needles. However, the internal restriction is deeper within the needle bore

Substantial Equivalent Basis

The proposed Phaco Chop Needle is substantially equivalent to the reusable Phaco Needles currently offered by Bausch & Lomb. They are the Standard Phaco Needle, MicroFlow Phaco Needle, MicroFlow+ Phaco Needle

Comparison Matrix

Components	Currently Marketed Standard Phaco Needle	Currently Marketed MicroFlow Needle	Currently Marketed MicroFlow Plus Needle	Proposed Phaco Chop Needle
Intended Use	Phaco needles are used for anterior segment surgery with Bausch and Lomb Microsurgical Systems	Phaco needles are used for anterior segment surgery with Bausch and Lomb Microsurgical Systems.	Phaco needles are used for anterior segment surgery with Bausch and Lomb Microsurgical Systems.	Phaco needles are used for anterior segment surgery with Bausch and Lomb Microsurgical Systems
Sterile/Non-Sterile	Sterile & Non-Sterile	Sterile & Non-Sterile	Sterile & Non-Sterile	Non-Sterile only
Single Use/Reusable	Single Use & Reusable	Single Use & Reusable	Single Use & Reusable	Reusable only
Tip Angle (degrees)	15, 30 & 45	0, 15, 30 & 45	0, 15, 30 & 45	30 & 45
Needle Tip OD (in.)	0.042	0.042	0.046	0.042
Needle Tip ID (in.)	0.036	0.036	0.036	0.036

Statement of Indications for Use

The Phaco Needles are intended for use with a Bausch & Lomb Millennium, Protegé or Premiere Microsurgical System for the emulsification of an opacified crystalline lens.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Bauch & Lomb, Inc.
c/o Dennis Pozzo
3365 Tree Ct. Industrial Blvd.
St. Louis, MO 63122-6694

Re: K041998
Trade/Device Name: Phaco Chop Needles
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacoemulsification Needles
Regulatory Class: Class II
Product Code: HQC
Dated: July 22, 2004
Received: July 26, 2004

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

Device Name: Phaco Chop Needle

Indications for Use:

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(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)

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

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Bausch & Lomb Surgical