K073023

Bausch & Lomb

510(k) Summary Statement
Bausch & Lomb Irrigation and Aspiration Handpieces

MAR 12 2008

Applicant's Name and Address

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

Contact Person

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

1. Identification of device

Common Name:	Irrigation/Aspiration (I/A) Handpieces
Trade Name:	Bausch & Lomb® Sterile Single-Use I/A Handpieces
Classification:	Class II Phacofragmentation system (21 CFR 886.4670
Device classification:	Class II (21 CFR 886.4670)
Pro Code:	86 HQC

2. Description of device

The Bausch & Lomb, Inc. Sterile Single-Use I/A Handpieces are accessories to the Bausch & Lomb, Inc. Stellaris Vision Enhancement System and the Bausch & Lomb, Inc. PREMIERE (Millennium) Microsurgical System. Both irrigation and aspiration functions are incorporated within one molded plastic handle, and operate simultaneously at a balanced rate to irrigate, maintain proper anterior chamber depth during a procedure, and remove cortical lens material, viscoelastic, and excess BSS used to bathe the anterior chamber. This combination feature allows access through a single incision, thus reducing trauma to the eye and improving surgical control. The Bausch & Lomb, Inc. family of Sterile Single-Use I/A Handpieces (containing the new plastic hand-held handle) currently consists of the models identified in Table 2.

3. Intended use

The Bausch & Lomb Sterile Single-Use I/A Handpieces are used following phacoemulsification, an anterior surgical procedure to fragment and remove a cataractous lens. The eye is infused with Balanced Salt Solution (BSS) via the irrigation function, while the cortical material, viscoelastic, and excess BSS is removed via the aspiration function. I/A handpieces are also used for polishing the capsular bag to remove residual lens epithelial cells from the capsular membrane following extraction of the lens material.

4. Substantial Equivalence

510(k)	Clearance Date	Device Description
K951463	10/27/1995	Storz I/A Handpieces (B&L)
K912739	4/7/2006	SITE Microsurgical System

A comparison of characteristics of the Bausch & Lomb, Inc., Sterile Single-Use I/A Handpieces to those of predicate devices, demonstrating substantial equivalence is found at the end of this document.

5. Technological Characteristics

The Bausch & Lomb, Inc., Sterile Single-Use I/A handpieces associated with this submission are a series of single handpieces, with different tip designs. One of the models requires a silicone irrigation sleeve. The handpiece tip configurations available are: straight, curved, angled, and hooked designs. The microsurgical system for which the handpieces are designed include the Bausch & Lomb, Inc., Stellaris Vision Enhancement System and the Bausch & Lomb, Inc., PREMIERE Millenium Microsurgical System. The finished product material composition is a plastic medical grade handle, and medical grade stainless steel tips on the models. The handpieces are for single use purposes.

6. Safety and Perfomance Testing:

Sterilty: Bausch & Lomb, Inc., Sterile Single-Use I/A Handpieces are provided sterile by gamma irradiation. Sterilization has been validated to a SAL of 10^{-6} for all standard panel of ophthalmic organisms in accordance with ANSI/AAMI/ISO TR13409 Standards.

Stability: Seal Integrity Test with dye penetration of radiated product; and a Microbial Barrier Test after accelerated aging at one and five years, in accordance with adopted Standards.

Biocompatibility: The following tests were conducted on the devices: cytotoxicity,, bioburden determination, LAL Endotoxin Test, and Particle Test. All tests were conducted on three separate lots of product manufactured at different times. The results indicated that all outcomes were within expected and acceptable limits of the tests.

All stability and biocompatibility testing was conducted under adopted international standards as follows:

Dye Penetration:	ANSI/AAMI/ISO 11607 (Annex C)
Microbial Barrier Test:	DIN 58953-6, DIN EN 868-1; ANSI/AAMI/ISO 11607
Cytotoxicity:	DIN EN ISO 10993-5-12, ISO 9363-1
Bioburden Determination:	DIN EN 1174, ISO 11737-1, USP 25 [61]
LAL Endotoxin Test:	DAB 1999 V.2, USP 25 [85], EP 2001, FDA Guideline
Particle Test:	USP 25 [788]

Verification and Validation Testing: Performance testing was conducted on the devices and their components in accordance with device design control requirements and found to meet requirements set forth in the design control plan.

7. Packaging

The Bausch & Lomb Inc., Sterile Single-Use I/A Handpieces are packaged in sealed packages subject to radiation sterilization and enclosed in an outer carton, labeled on the carton and the immediate package container.

8. Clinical Data:

The Bausch & Lomb, Inc., Sterile Single-Use I/A Handpieces are substantially equivalent to Bausch & Lomb Inc., I/A handpieces currently available in the marketplace. Clinical investigations were deemed as not necessary for the planned marketing of the new model handpieces.

9. See following pages

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9. Table 1. Comparison Chart of Predicate Devices

MANUFACTURER	B&L I/A HANDPIECES [Subject 510(k)]	STORZ (B&L) I/A HANDPIECES K961463	SITE MICROSURGICAL SYSTEM K912739
Indication for Use	The Bausch & Lomb™ Sterile Single-Use I/A Handpieces are used following phacoemulsification, an anterior surgical procedure to fragment and remove a cataractous lens. I/A handpieces are also used for polishing the capsular bag.	Irrigation/aspiration of lens material and viscoelastic material; capsule polishing: Models B4973 and B4973CAV for viscoelastic material removal specifically	Irrigation/aspiration: Models MVS1082 and E4750121 infusion handpieces for use in bimanual procedures specifically
Type of handpiece/components	See Table 2.	See Table 2.	See Table 2.
-Number of single handpieces	23	13	10
-Number of handpieces for use with interchangeable tips	0	0	1
-Number of interchangeable tips	0	0	unknown
Models requiring a silicone irrigation sleeve	85785S	MVS 1066	none
Handpiece tip configurations	Straight, curved, angled, and hooked designs	Straight, curved, angled, and hooked designs	Straight and curved designs
Microsurgical system for which handpieces are designed	B&L Stellaris Vision Enhancement System and B&L PREMIERE Millenium Microsurgical System.	Storz Protégé and PREMIERE for MVS Models; Storz DAISY and United Sonics unit for B4973; Cavitron unit for B4973 CAV.	SITE TXR Microsurgical System 2200
Finished Product Material Composition	Medical grade plastic handle; medical grade stainless steel on most models	316L, stainless steel; medical grade silicone on most models	Stainless steel; other materials unknown
Handpiece Reusable	No	Yes	Yes

Bausch & Lomb

Table 2. Sterile Single-Use Handpieces and Corresponding Predicate Reusable I/A Handpieces

Sterile Single Use I/A Handpieces		Predicate Reusable I/A Handpiece		
Model No.	**Type**	**Model No.**	**Type**	**510(k) number**
Coaxial Irrigation/Aspiration Handpieces				
85782S	I/A Handpiece, straight, 17GA, 12/box	MVS 1063	I/A Handpiece Straight, 17GA	K951463
85783S	I/A Handpiece, curved, 17GA, 12/box	MVS 1063 S	I/A Handpiece Curved, 17GA	K951463
85783ST	I/A Handpiece, curved, 17GA, 12/box	MVS 1063 S	I/A Handpiece Curved, 17GA	K951463
85784S	I/A Handpiece, tip 45°, 17GA, 12/box	MVS 1063 CX	I/A Handpiece Tip 45°, 17GA	K951463
85784ST	I/A Handpiece, tip 45°, 17GA, 12/box	MVS 1063 CX	I/A Handpiece Tip 45°, 17GA	K951463
85785S	I/A Handpiece, straight with sleeve, 12/box	MVS 1066	I/A Handpiece, straight with sleeve	K951463
85786S	I/A Handpiece, tip 90°, 16GA, 12/box	DP9730	I/A Tip 90° for use with handle DP9721	K951463
85786ST	I/A Handpiece, tip 90°, 16GA, 12/box	DP9730	I/A Tip 90° for use with handle DP9721	K951463
85794ST	I/A Handpiece curved with Sleeve 1.8 12/box	DP9734	Curved I/A Tip with sleeve for use with DP9721 Handle	K951463
85795ST	I/A Handpiece tip 45° with Sleeve 1.8 12/box	DP9733	45° I/A Tip with sleeve for use with DP9721 Handle	K951463
Bimanual Aspiration Handpieces				
85780S	Aspiration Handpiece, sterile, 21GA, 12/box	E4753A23	Aspiration Handpiece, 0.3mm Port	K912739
85901S19	Aspiration Handpiece, 19GA, 12/box	MVS1083	Aspiration Handpiece, 19GA	K912739
85901S20	Aspiration Handpiece, 20GA, 12/box	MVS1083	Aspiration Handpiece, 19GA	K912739
Bimanual Irrigation Handpieces				
85781S	Irrigation Handpiece, sterile, 21GA, 12/box	E4750I21	Irrigation Handpiece 21GA	K912739
85787S	Irrigation Handpiece, smooth tip, 21GA, 12/b	E4750I21	Irrigation Handpiece 21GA	K912739
85787ST	Irrigation Handpiece, smooth tip, 21GA, 12/b	E4750I21	Irrigation Handpiece 21GA	K912739
85788S	Irrigation Handpiece, central port, 21GA, 12/	E4750I21	Irrigation Handpiece 21GA	K912739
85902S19	Irrigation Handpiece, 19GA, 12/box	MVS1082	Irrigation Handpiece, 19GA	K912739
85902S20	Irrigation Handpiece, 20GA, 12/box	MVS1082 20	Irrigation Handpiece, 20GA	K912739
85902ST19	Irrigation Handpiece, 19GA, 12/box	MVS1082	Irrgation Handpiece, 19GA	K912739
Bimanual Irrigation Choppers				
85903S19	Irrigation Chopper, 19GA, 12/box	MVS1096 19	Irrigation Chopper, 19GA	K951463
85903S20	Irrigation Chopper, 20GA, 12/box	MVS1096 19	Irrigation Chopper, 19GA	K951463
85903ST19	Irrigation Chopper, 19GA, 12/box	MVS1096 19	Irrigation Chopper, 19GA	K951463

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bausch & Lomb, Inc.
c/o Ms. Lisa Graney
Manager, Global Regulatory Affairs
1400 North Goodman St.
Rochester, NY 14609

MAR 12 2008

Re: K073023

Trade/Device Name: Bausch & Lomb (B&L) Sterile Single-Use I/A Handpieces
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: February 19, 2008
Received: February 21, 2008

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 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.

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): K073023

Device Name: Bausch & Lomb™ Sterile Single-Use I/A Disposable Handpieces

Indication for Use

The Bausch & Lomb™ Sterile Single-Use I/A Handpieces are used following phacoemulsification, an anterior surgical procedure to fragment and remove a cataractous lens. The eye is infused with Balanced Salt Solution (BSS) via the irrigation function, while the cortical material, viscoelastic, and excess BSS is removed via the aspiration function. I/A handpieces are also used for polishing the capsular bag to remove residual lens epithelial cells from the capsular membrane following extraction of the lens material.

(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)
Division of Ophthalmic Devices

510(k) Number K073023

BAUSCH & LOMB STERILE SINGLE-USE I/A STELLARIS HANDPIECE MODELS
510(K) K073023

Model No. Sterile Single Use I/A Handpieces	Type
Coaxial Irrigation/Aspiration Handpieces	
85782S	I/A Handpiece Straight, 17GA
85783S	I/A Handpiece, curved, 17 GA
85783ST	I/A Handpiece, curved, 17 GA
85784S	I/A Handpiece, tip 45°, 17 GA
85784ST	I/A Handpiece, Tip 45°, 17 GA
85785S	I/A Handpiece, straight w/ sleeve
85786S	I/A Handpiece, tip 90°, 16 GA
85786ST	I/A Handpiece, tip 90°, 16 GA
85794ST	I/A Handpiece, curved w/ Sleeve 1.8
85795ST	I/A Handpiece
Bimanual Aspiration Handpieces	
Sterile Single-Use I/A Handpiece Model No.	Type
85780S	Aspiration Handpiece, sterile, 21 GA
85901S19	Aspiration Handpiece, sterile, 19 GA
85901S20	Aspiration Handpiece, sterile, 20 GA
Bimanual Irrigation Handpieces	
Sterile Single-Use I/A Handpiece Model No.	Type
85781S	Irrigation Handpiece, sterile, 21 GA
85787S	Irrigation Handpiece, smooth tip, 21 GA
85787ST	Irrigation Handpiece, smooth tip, 21 GA
85788S	Irrigation Handpiece, central port, 21 GA
85902S19	Irrigation Handpiece, sterile, 19 GA
85902S20	Irrigation Handpiece, sterile, 20 GA

85902ST19	Irrigation Handpiece, sterile, 19 GA
Bimanual Irrigation Choppers	
Sterile Single-Use I/A Handpiece Model No.	Type
85903S19	Irrigation Chopper, 19 GA
85903S20	Irrigation Chopper, 20 GA
85903ST19	Irrigation Chopper, 19 GA