K082132

Bausch & Lomb

AUG 28 2008

510(k)
SUMMARY OF SAFETY AND EFFECTIVENESS

The following information is provided in accordance with requirements of 21CFR 807.92:

Contact Person: Ned Luce
Director Regulatory Affairs
Global Surgical Devices

Date Prepared: July 24, 2008

Proprietary Name: Bausch & Lomb D4600A Air Exchange Line Pack

Common/Usual Name: Ophthalmic surgical system accessory pack for posterior segment procedures.

Classification Name: System, Phacofragmentation (86 HQC)

Device Description/Intended Use:

The Bausch & Lomb D4600A Air Exchange Line Pack is intended to be used as an accessory to the Bausch & Lomb Stellaris (K063331) Microsugrical System. The device is for use as an air exchange system during posterior segment ophthalmic surgical procedures. The D4600A Air Exchange Line provides the initial pathway through which air generated by the microsurgical system is routed into the posterior chamber of the eye.

Predicate Device: The proposed Bausch & Lomb D4600A Air Exchange Line Pack is substantially equivalent to the existing Bausch & Lomb D4600 Air Exchange Line Pack (K962131) for use with the Bausch & Lomb MILLENNIUM® Microsurgical System (K961310). The subject device may be used with each of these systems.

Predicate Comparison: A chart comparing the Bausch & Lomb D4600A to the predicate Bausch & Lomb D4600 device demonstrates substantial equivalence is attached.

DEVICE COMPARISON CHART
Bausch & Lomb D4600A Air Exchange Line Pack

DEVICE	Bausch & Lomb D4600A Subject Device	Storz D4600 K962131
Intended Use	To deliver air to the eye during posterior surgical procedures	To deliver air to the eye during posterior ophthalmic surgical procedures
Recommended System	Bausch & Lomb STELLARIS® or MILLENNIUM® Microsurgical Systems	Bausch & Lomb PREMIERE® Microsurgical System
Instructions for Use Included	Yes	Yes
Single Patient Use?	Yes	Yes
Provided Sterile?	Yes	Yes
Sterilizataion Method	Gamma Irradiation (Cobalt)	Gamma Irradiation
Packaging	Singly in Tyvek® and PET/PE Pouch 6 pouches per Box	Singly in Tyvek® and PET/PE Pouch 10 pouches per Box

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bausch & Lomb, Inc.
c/o Ned Luce
Director Regulatory Affairs
Global Surgical Devices
1400 North Goodman Street
Rochester, NY 14609

AUG 28 2008

Re: K082132
Trade/Device Name: Bausch & Lomb™ D4600A Air Exchange Line Pack
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: II
Product Code: HQC
Dated: July 24, 2008
Received: July 29, 2008

Dear Mr. Luce:

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.
Director
Division of Ophthalmic and Ear, Nose
and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K082132

Indications for Use

510(k) Number (if known): K082132

Device Name: Bausch & Lomb D4600A Air Exchange Line Pack

Indications for Use:

The Bausch & Lomb™ D4600A Air Exchange Line Pack is intended to be used as an accessory to the Bausch & Lomb STELLARIS® and Bausch & Lomb MILLENNIUM®, Microsurgical Systems for use in air and fluid exchange during posterior segment ophthalmic procedures.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bruce Drum

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

510(k) Number K082132