K071043

AUG - 2 2007

510(K) SUMMARY
BOSTON XO (hexafocon A), BOSTON EO (enflufocon B), and BOSTON ES (enflufocon A) Rigid Gas Permeable Contact Lenses for Daily Wear

1. Applicant's Name and Address

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

2. Contact Person

Debra Ketchum
Manager,Global Regulatory Affairs
Bausch & Lomb, Inc.
1400 North Goodman Street
Rochester, NY 14609
(585) 338-8638

3. Identification of Device

Common Name: contact lens-rigid gas permeable (hydrophobic)

Trade Name: Boston XO (hexafocon A), Boston EO (enflufocon B), and Boston ES (enflufocon A) Daily Wear Contact Lens

Classification: Class II ophthalmic (21CFR 886.5916)

Device classification: Class II (21 CFR 886.5916)
Pro Code: HQD

Predicate Devices:

K053124 and K013762: Boston XO (hexafocon A), Boston EO (enflufocon B), Boston ES (enflufocon A)

510(k)	Clearance Date	Device Description
K053124	1/30/2006	Boston XO, Boston EO, Boston ES
K013762	4/3/2002	Boston XO, Boston EO, Boston ES

4. Description of device

Boston XO (hexafocon A) is a rigid gas permeable material, composed of siloxanyl fluoromethacrylate copolymer available with or without an ultraviolet absorber.

The Boston XO (hexafocon A), Boston EO (enflufocon B) and Boston ES (enflufocon A) are rigid gas permeable contact lens materials composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer available with or without an ultraviolet absorber.

The physical and optical properties of the lenses are:

Property	BOSTON XO	BOSTON EO	BOSTON ES
Specific Gravity	1.27	1.23	1.22
Refractive Index	1.425	1.429	1.443
Visible Light Transmittance	92% average	92% average	92% average
UV Blocker	UV 49	UV 49	UV 49
Water Content	<1%	<1%	<1%
Wetting Angle	49^0	49^0	52^0
Oxygen Permeability (Dk)***	140* 100**	82* 58**	36* 18**

*gas to gas method
**polarographic method (ISO)
***polarographic method (FATT) (x 10^{-11} (cm^2O_2 x cm)/cm^2 x sec x mmHg)@35^0C

5. Intended use

The Boston XO (hexafocon A), Boston EO (enflufocon B), and Boston ES (enflufocon A) Rigid Gas Permeable Contact Lenses are indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and not-aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery. The lenses may be disinfected using a chemical disinfection system only.

6. Description of Safety and Substantial Equivalence

The safety and efficacy of the Boston XO (hexafocon A), Boston EO (enflufocon B), and Boston ES (enflufocon A) was demonstrated in original 510(k) Premarket Notifications as follows:

- K000795, cleared May 25, 2000
- K013762, cleared April 3, 2002
- K053124, cleared January 30, 2006

Safety and efficacy for all subject devices were determined in prior 510(k) clearances. The addition of the UV blocker to the BOSTON XO material has been demonstrated as safe as evidenced by preclinical testing as required in current Pre-Market Notification Guidance for Daily Wear Contact Lenses, May 12, 1994. All three materials will now use the same UV blocker.

7. Clinical data:

Clinical studies for the BOSTON XO (hexafocon A), BOSTON EO (enflufocon B), and BOSTON ES (enflufocon A) materials have been deemed as not necessary in support of their clearance as no new or additional questions of safety or effectiveness have been raised as a result of the change of UV blocker in BOSTON XO (hexafocon A). BOSTON EO (enflufocon B) and BOSTON ES (enflufocon A) already incorporate the same UV blocker.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 2 2007

Bausch & Lomb, Inc.
c/o Debra Ketchum
1400 North Goodman Street
Rochester NY 14609-3547

Re: K071043
Trade/Device Name: Boston XO (hexafocon A), Boston EO (enflufocon B), and Boston ES (enflufocon A) Daily Wear Rigid Gas Permeable Contact Lenses
Regulation Number: 21 CFR 886.5916
Regulation Name: Rigid gas permeable contact lens
Regulatory Class: Class II
Product Code: HQD
Dated: July 17, 2007
Received: July 18, 2007

Dear Ms. Ketchum:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

M B Eydelman, MD

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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071043

Device Name: Boston XO (hexafocon A), Boston EO (enflufocon B), and Boston ES (eflufocon A) Daily Wear Contact Lens

Indication for Use

Boston XO (hexafocon A), Boston EO (enflufocon B) and Boston ES (enflufocon A) Rigid Gas Permeable Contact Lenses are indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism, and presbyopia) in aphakic and not aphakic persons with non-diseased eyes. Also, the lenses may be prescribed in otherwise non-diseased eyes that require a rigid contact lens for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty or refractive (e.g. LASIK) surgery. The lenses may be disinfected using a chemical disinfection system only.

(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 Ear,
Nose and Throat Devises

510(k) Number K071043