K053124

JAN 3 0 2006

510(k) SUMMARY
SUMMARY OF SAFETY AND EFFECTIVENESS

BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) AND BOSTON XO® (hexafocon A) RIGID GAS PERMEABLE CONTACT LENSES

1. SUBMITTER INFORMATION

Bausch & Lomb Incorporated
1400 North Goodman Street
Rochester, NY 14609

Contact Person: Lisa Graney
Manager, Global Regulatory Affairs
Telephone No.: (585) 338-6612

2. DEVICE NAME

Classification Name: rigid gas permeable (hydrophobic) contact lens

Proprietary Name: BOSTON ES (enflufocon A), BOSTON EO (enflufocon B), and BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lenses

3. PREDICATE DEVICES

Lens Dynamics Inc., Dyna Intra-Limbal Lens (enflufocon A or hexafocon A) Rigid Gas Permeable Contact Lens, cleared in 510(k) Premarket Notification K020006, and Rose K Post Graft (hexafocon A or enflufocon B) Rigid Gas Permeable Contact Lens, cleared in 510(k) Premarket Notification K013646, have been selected as the predicate devices for the BOSTON ES (enflufocon A), BOSTON EO (enflufocon B), and BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lenses.

4. DESCRIPTION OF DEVICE

The BOSTON ES (enflufocon A) and BOSTON EO (enflufocon B) are rigid gas permeable Contact Lens materials composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer with an ultraviolet absorber.

BOSTON XO (hexafocon A) is a rigid gas permeable contact lens material, composed of siloxanyl fluoromethacrylate copolymer containing an ultraviolet absorber.

The color additives conform to 21 CFR Part 74 and/or 21 CFR Part 73. The lenses may also be supplied clear (no tint).

The physical / optical properties of the lenses are:

Property	BOSTON ES	BOSTON EO	BOSTON XO
Specific Gravity	1.22	1.23	1.27
Refractive Index	1.443	1.429	1.415
Visible Light Transmittance	> 85%	> 85%	> 92%
Water Content	<1%	<1%	<1%
Wetting Angle	52°	49°	49°
Oxygen Permeability (Dk)***	36* 18**	82* 58**	140* 100**

*gas to gas method
polarographic method (ISO/Fatt) *{x 10^{-11} (cm^3 O_2 • cm)/ (cm^2 • sec • mmHg) @ 35° C}

5. INDICATIONS FOR USE

The BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) and BOSTON XO® (hexafocon 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 BOSTON ES (enflufocon A), BOSTON EO (enflufocon B), and BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lenses was demonstrated in 510(k) Premarket Notifications as follows: K943177 cleared on August 25, 1994; K980741 cleared on May 11, 1998; and K000795 cleared on May 25, 2000, respectively. The most recent Premarket Notification for all three materials (Boston ES, EO, and XO) was 510(k) K013762, cleared April 3, 2002, for a new indication for keratoconus.

BOSTON ES (enflufocon A), BOSTON EO (enflufocon B), and BOSTON XO (hexafocon A) Rigid Gas Permeable Contact Lenses are substantially equivalent to Lens Dynamics Inc., Dyna Intra-Limbal Lens (enflufocon A or hexafocon A) Rigid Gas Permeable Contact Lens, cleared in 510(k) Premarket Notification K020006, and Rose K Post Graft (hexafocon A or enflufocon B) Rigid Gas Permeable Contact Lens, cleared in 510(k) Premarket Notification K013646, including an indication for the management of irregular corneal conditions such as keratoconus, pellucid marginal degeneration, or following penetrating keratoplasty.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 0 2006

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

Re: K053124
Trade/Device Name: BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) and BOSTON XO® (hexafocon A) 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: November 4, 2005
Received: November 15, 2005

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 Office of Compliance at (301) 827-8910. 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/industry/support/index.html.

Sincerely yours,

Malvina B. Eydelman, M.D.
Acting Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Bausch & Lomb
1400 North Goodman Street
Rochester, NY 14609

Indications for Use Statement

510(k) Number (if known): K053124

Device Name: BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) and BOSTON XO® (hexafocon A) Rigid Gas Permeable Contact Lenses

Indications for Use:

The BOSTON ES® (enflufocon A), BOSTON EO® (enflufocon B) and BOSTON XO® (hexafocon A) Rigid Gas Permeable Contact Lenses are indicated for the daily wear correction of refractive ametropia (myopia, hyperopia, astigmatism, 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.

Prescription Use √ **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)

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

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