510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BOSTON XO

1. SUBMITTER INFORMATION:

Polymer Technology
Global Vision Care
1400 N. Goodman Street
Rochester, New York 14603-0450

2. CONTACT PERSON:

Debra Ketchum
Manager, Regulatory Affairs

Address:	1400 North Goodman Street P.O. Box 450 Rochester, New York 14603-0450
Telephone No.:	(716) 338-8638
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E-mail Address:	dketchum@bausch.com

3. DEVICE IDENTIFICATION:

Classification Name:	Rigid Gas Permeable (hydrophobic) Contact Lens Material
Proprietary Name:	BOSTON XO (hexafocon A) Contact Lens Material
Common Name:	fluoro silicone acrylate rigid gas permeable contact lens material

4. PREDICATE DEVICE:

BOSTON ES (enflufocon A) has been selected as the predicate device for *BOSTON XO* (hexafocon A).

5. DESCRIPTION OF THE DEVICE:

The *BOSTON XO* Contact Lens Material, hexafocon A, is composed of aliphatic fluoroitaconate siloxanyl methacrylate copolymer.

The color additives conform to 21 CFR part 74.3206. The hexafocon A material has an oxygen permeability, DK of 100, a specific gravity of 1.26, and the lens visible light transmittance of at least 70%. The hexafocon A name has been adopted by the United States Adopted Names Council (USAN).

6. INDICATIONS FOR USE:

The *BOSTON XO* contact lens material is indicated for daily wear for the correction of refractive ametropia (myopia, hyperopia, astigmatism and presbyopia) in aphakic and not-aphakic persons with nondiseased eyes. The lens may be disinfected using a chemical disinfection system only.

7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:

A series of preclinical testing were performed to demonstrate the safety and effectiveness of the *BOSTON XO* contact lens material. The results of all testing demonstrated that the safety and effectiveness of the *BOSTON XO* is equivalent to the currently marketed BOSTON ES contact lens material. A summary of these results from the preclinical studies is presented below.

Toxicology:

In-Vitro Cytotoxicity:
USP Agar Diffusion Cytotoxicity was completed in accordance with USP XXII. The test article meets the requirements of the Agar Diffusion Test.

Acute Ocular Irritation:
Acute Ocular Irritation test was performed and produced no ocular irritation.

Systemic Injection
The lens material meets the requirements of the Systemic Injection Test and is considered non-toxic.

Shelf Life:
The *BOSTON XO* (hexafocon A) is a hydrophobic rigid gas permeable contact lens material with <1% water content. This material will be shipped dry. The data presented supports substantial equivalence of this *BOSTON XO* (hexafocon A) contact lens material to the already marketed BOSTON ES (enflufocon A) contact lens material. Based on the Premarket Notification Guidance Document for Daily Wear Contact Lenses, May 12, 1994, shelf-life studies are not required for clearance of this material.

Solution Compatibility:
Studies were conducted on blue tinted lens material with the ultraviolet light absorber. Lenses were run through 30 cycles of cleaning and conditioning to establish the compatibility of the lens material with the recommended care regimen. The parameters of ultraviolet and visible light (UV/vis) spectra, base curve, lens diameter, power and surface quality were recorded prior to and upon completion of 30 cycles. Initial and final data were compared. There were no significant changes to lens parameters after 30 complete cycles.

Clinical Testing

Below is a summary of the clinical study carried out to evaluate the safety and efficacy of the *BOSTON XO* (hexafocon A) contact lens material when used as a daily wear contact lens for the correction of visual acuity.

A total of 128 eyes (64 patients) were entered into the study by 3 Investigators. Prior to entry into this study each patient was required to read and sign a Statement of Informed Consent. All patients who signed a Statement of Informed Consent are accounted for in this report. Of the 128 eyes (64 patients enrolled), 102 eyes (51 patients) completed the study.

The safety and efficacy measures for this study were:

Safety: Adverse Events, Positive Slit Lamp Findings, Symptoms/Complaints and Keratometry Changes

Efficacy: Refractive Changes, Lens Visual Acuity, Lens VA Line Changes, Lens Deposits, and Lens Wettability.

The sponsor concludes that *BOSTON XO* (hexafocon A) contact lens material is equivalent in safety and efficacy to the predicate device, Boston ES (enflufocon A).

8. SUBSTANTIAL EQUIVALENCE

The *BOSTON XO* contact lens material is substantially equivalent to the currently marketed BOSTON ES contact lens material, which was cleared in 510(k) Premarket Notification No. K943177 on August 25, 1994. The difference between the two devices is a change in the components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2000

Ms. Debra L.B. Ketchum
Manager. Regulatory Affairs
Polymer Technology
Global Vision Care
1400 N Goodman Street
P.O. Box 450
Rochester, NY 14603-0450

Re: K000795
Trade Name: BOSTON XO Contact Lens
Regulatory Class: II
Product Code: 86 HQD
Dated: March 10, 2000
Received: March 13, 2000

Dear Ms. Ketchum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Nancy C. Brogdon

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

Polymer Technology
1400 North Goodman Street
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Rochester, NY 14603-0450

Indications for Use Statement

510(k) Number (if known): K 000795

Device Name: BOSTON XO

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 of Ophthalmic Devices
510(k) Number K000795