SEP 1 2 2001

K011945

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BOSTON® EQUALENS® and BOSTON® EQUALENS® II RGP Contact Lenses Wet Shipped In BOSTON® Advance® Comfort Formula Conditioning Solution And Stored For Up To 30 Days

1. **SUBMITTER INFORMATION:**

Polymer Technology
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 30450
Rochester, New York 14603-0450
Telephone No.: (716) 338-8638
Fax No.: (716) 338-0702
E-mail Address: dketchum@bausch.com

3. **DEVICE IDENTIFICATION:**

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

4. **PREDICATE DEVICE:**

BOSTON XO (hexafocon A) RGP Contact Lenses Wet Shipped and up to 30 day storage in Boston Advance Comfort Formula Conditioning Solution, 510(k) K002025 cleared on October 31, 2000.

5. **DESCRIPTION OF THE DEVICE:**

BOSTON EQUALENS (itafluorofocon A) and EQUALENS II (oprifocon A) Contact Lenses are composed of fluoro silicone acrylate copolymers wet shipped in Boston Advance Comfort Formula Conditioning Solution and stored for up to 30 days.

6. INDICATIONS FOR USE:

BOSTON EQUALENS (itafluorofocon A) and EQUALENS II (oprifocon A) RGP 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 nondiseased eyes. The lens may be disinfected using a chemical disinfecting system only.

7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:

The applicant performed stability, compatibility, and microbiology testing on BOSTON EQUALENS and BOSTON EQUALENS II RGP Contact Lenses wet shipped in Boston Advance Comfort Formula Conditioning Solution and stored for up to 30 days.

Stability/Compatibility:
Silicone acrylate (SA) and fluorosilicone acrylate (FSA) tinted rigid gas permeable contact lenses were subjected to a thirty-day soak in Boston Advance Comfort Formula Conditioning Solution according to the lens compatibility protocol. The average changes for each parameter (diameter, base curve and power), relative to the initial measurements were determined and compared to the DRAFT ISO/CD 8321-2: Optics and Optical Instruments – Contact Lenses- Part 1: Specifications for rigid corneal and scleral contact lenses.

After soaking in the contact lens carrying cases at room temperature for thirty days the silicone acrylate and fluoro silicone acrylate rigid gas permeable contact lenses were determined to be physically compatible with Boston Advance Comfort Formula Conditioning Solution.

Microbiology
A bioburden study was completed. A set of test lenses was cleaned with Boston Laboratory Lens Cleaner and subjected to bioburden testing. In this test, two sets of lenses were tested to validate the storage in Boston Advance Comfort Formula after 30 days. One set was stored dry (control) and the other set was stored in Boston Advance Comfort Formula. This established the "cleanliness" of the test samples prior to entering the stability study. Testing showed that the colony forming units (CFU) per lens was less than 10. The acceptance criteria is 100 CFU per lens. Testing showed that the colony forming units (CFU) per lens was less than 10. The acceptance criteria is 100 CFU per lens.

8. SUBSTANTIAL EQUIVALENCE

BOSTON EQUALENS and EQUALENS II RGP Contact Lenses wet shipped in Boston Advance Comfort Formula Conditioning Solution and stored for up to 30 days are substantially equivalent to the currently marketed BOSTON Rigid Gas Permeable Contact Lens Wet Shipped In Boston Advance Comfort Formula Conditioning Solution and stored for up to 30 days, 510(k) Premarket Notification No. K002025.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 2 2001

Polymer Technology
c/o Ms. Debra Ketchum
1400 N. Goodman St.
P.O. Box 30450
Rochester, NY 14603-0450

Re: K011945
Trade/Device Name: BOSTON[R] EQUALENS[R] (itafluorofocon A) and BOSTON[R] EQUALENS[R] II (oprifocon A) Rigid Gas Permeable Contact Lenses (Wet Shipped and up to 30 day storage in Boston Advance Comfort Formula Conditioning Solution)
Regulation Number: 21 CFR 886.5916
Regulatory Class: Class II
Product Code: HQD
Dated: June 20, 2001
Received: June 21, 2001

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 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). 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,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Polymer Technology
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P.O. Box 30450
Rochester, NY 14603-0450

Indications for Use Statement

510(k) Number (if known): K011945

Device Name: BOSTON® EQUALENS® (itafluorofocon A) RGP Contact Lens
BOSTON® EQUALENS® II (oprifocon A) RGP Contact Lens

Indications for Use:

BOSTON EQUALENS (itafluorofocon A) and BOSTON EQUALENS II (oprifocon A) RGP 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 nondiseased eyes. The lens may be disinfected using a chemical disinfecting 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_____

Myra Smith
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K011945