8/11/99

K983836

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

FOR

BOSTON® ENHANCED ORIGINAL FORMULA CONDITIONING SOLUTION

1. SUBMITTER INFORMATION:

Polymer Technology,
a division of Wilmington Partners, L.P.
1400 N. Goodman Street
Rochester, New York 14692-0450

2. CONTACT PERSON:

Debra Ketchum
Manager, Regulatory Affairs
Address: 1400 North Goodman Street
Rochester, New York 14692
Telephone No.: (716) 338-8638
Fax No.: (716) 338-0702

3. DEVICE IDENTIFICATION:

Classification Name:	Rigid Gas Permeable Contact Lens Solution
Proprietary Name:	Boston® Enhanced Original Formula Conditioning Solution
Common Name:	Contact Lens Conditioning Solution

4. PREDICATE DEVICE:

The currently marketed Boston® Conditioning Solution, approved under PMA P820070 on November 17, 1983, has been selected as the predicate device for the modified *Boston® Enhanced Original Formula Conditioning Solution.*

5. DESCRIPTION OF THE DEVICE:

The modified *Boston® Enhanced Original Formula Conditioning Solution* is a sterile conditioning solution used in the care of rigid gas permeable contact lenses and is indicated for the wetting, disinfecting and soaking after cleaning and rinsing of fluoro silicone acrylate and silicone acrylate contact lenses. This product is a sterile, buffered solution, preserved with chlorhexidine gluconate and edetate disodium.

6. INDICATIONS FOR USE:

The modified *Boston® Enhanced Original Formula Conditioning Solution* is indicated for use in the wetting, disinfecting and soaking after cleaning and rinsing of fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

7. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:

A series of preclinical testing was performed to demonstrate the safety and effectiveness of the modified *Boston® Enhanced Original Formula Conditioning Solution*. A summary of the results from the preclinical tests 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. The solution did not cause any significant irritation to the ocular tissues of the laboratory animals.

Microbiology:

Preservative Effectiveness:
Studies were performed to evaluate the preservative efficacy of the modified *Boston® Enhanced Original Formula Conditioning Solution* in 1 oz. round containers and in 4 oz. oval containers. The results of these tests demonstrate that the modified *Boston® Enhanced Original Formula Conditioning Solution* meets the requirements of the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997* and the *ISO Draft Standard*.

The results of all testing demonstrated that the safety and effectiveness of the modified *Boston® Enhanced Original Formula Conditioning Solution* is equivalent to the currently marketed Boston® Conditioning Solution.

Disinfection Efficacy:

The ISO FDA Regimen Procedure for Disinfecting Regimens was performed to evaluate the disinfecting efficacy of the modified *Boston® Enhanced Original Formula Conditioning Solution.* The results of this evaluation demonstrate that the product meets the FDA performance criteria for regimen evaluation as described in the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997*, and the *Draft Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, April 1, 1996.*

Shelf Life:

Expiration dating will be established based on the Shelf-life Protocol in accordance with the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997*, and the *Draft Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, April 1, 1996.*

Solution Compatibility:

BOSTON IV (silicone acrylate) and BOSTON ES (fluoro silicone acrylate) tinted rigid gas permeable contact lenses were subjected to thirty repeated cycles with Boston Cleaner and the modified *Boston® Enhanced Original Formula Conditioning Solution.*

After thirty repeated cycles with Boston Cleaner and the modified *Boston® Enhanced Original Formula Conditioning Solution*, all of the physical and lens parameters tested for BOSTON IV and BOSTON ES rigid gas permeable tinted contact lenses were within ISO specifications for rigid corneal and scleral contact lenses. There was no change in the cosmetic appearance.

Wetting Angle:

This study evaluated the retention of the modified *Boston® Enhanced Original Formula Conditioning Solution* and the currently marketed Boston Conditioning Solution on two selected RGP lens materials, BOSTON IV (silicone acrylate) and BOSTON ES (fluoro silicone acrylate) tinted rigid gas permeable contact lenses. Dynamic contact angle (DCA) analysis was the method chosen to measure the desorption of solution from the lens material surface. The results of the DCA testing indicate that the modified *Boston® Enhanced Original Formula Conditioning Solution* maintains the wettability of the surface better than the currently marketed Boston Conditioning Solution.

8. SUBSTANTIAL EQUIVALENCE:

The modified *Boston® Enhanced Original Formula Conditioning Solution* is substantially equivalent to the currently marketed Boston Conditioning Solution, approved November 17, 1983 under PMA P820070, in that both products are formulated similarly, with the same indications, usage, and aspects of manufacturing.

9. CLINICAL:

The purpose of this study is to demonstrate that the modified *Boston® Enhanced Original Formula Conditioning Solution* is substantially equivalent in safety and efficacy to the currently marketed BOSTON Conditioning Solution when used with currently marketed silicone acrylate and fluoro-silicone acrylate rigid gas permeable contact lenses. This controlled clinical study was designed in accordance with the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997.*

A total of 212 eyes (106 patients) were entered into the study by 7 Investigators. Of the 212 eyes (106 patients) enrolled, 36 eyes (18 patients) were non-dispensed.

The data from the study were examined using descriptive statistics, tests for normality, analysis of variance and/or t-tests where appropriate. Analysis of all data from this study showed no clinically significant differences between the Test and Control Groups.

Based on these data, the Sponsor concludes that the modified *Boston Enhanced Original Formula Conditioning Solution* is substantially equivalent in safety and efficacy to the currently marketed Boston Original Conditioning Solution.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 1999

Ms. Debra Ketchum
Manager, Regulatory Affairs
Polymer Technology,
a division of Wilmington Partners, L.P.
1400 North Goodman St.
Rochester, New York 14692-0450

Re: K983836
Trade Name: Boston ® Enhanced Original Formula Conditioning Solution
Regulatory Class: II
Product Code: 86 MRC
Dated: January 28, 1999
Received: January 29, 1999

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) 594-4613. 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" (21 CFR 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/dsmamain.html".

Sincerely yours,

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

Enclosure

Polymer Technology,
a division of Wilmington Partners, L.P.
1400 North Goodman Street
Rochester, NY 14692-0450

Indications for Use Statement

510(k) Number (if known): K983836

Device Name: Boston® Enhanced Original Formula Conditioning Solution

Indications for Use:

Boston® Enhanced Original Formula Conditioning Solution is indicated for use in wetting, disinfecting and soaking after cleaning and rinsing of fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

(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 X

Mgn Smith

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K983836