

8. STATEMENT OF EQUIVALENCE:

The *Boston® Liquid Enzymatic Cleaner* has the same indications for use as Alcon OPTI-ZYME® Enzymatic Cleaner, which was approved under PMA P820001. Substantial equivalence is also claimed with two other currently marketed enzymatic cleaner for rigid gas permeable contact lenses. The first is Bausch & Lomb ReNu® 1 Step™ Enzymatic Cleaner, which, like *Boston® Liquid Enzymatic Cleaner*, contains a proteolytic enzyme (subtilisin) as the active cleaning agent. Bausch & Lomb ReNu® 1 Step™ Enzymatic Cleaner was approved under PMA P850093/S3. The second is Alcon OPTI-FREE® SupraCLENS Daily Protein Remover, which is also a liquid enzymatic cleaner that is indicated for use to clean fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses. OPTI-FREE® SupraCLENS was cleared under PMA No. P820001/S21.

9. PRE-CLINICAL:

A series of *in-vitro* and *in-vivo* preclinical chemical, toxicological, and microbiological studies were performed to assess the safety and effectiveness of *Boston® Liquid Enzymatic Cleaner*. Testing was carried out in accordance with *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*. A description of those tests can be found below.

Toxicology:

An *in vitro* biological reactivity (Agar Diffusion, USP 23, 1995, Chapter 87, 1698) test was conducted using Boston IV (silicone acrylate) and Boston ES (fluoro silicone acrylate) Rigid Gas Permeable Contact Lenses treated with lens care regimens employing BOSTON Conditioning Solution, BOSTON ADVANCE Comfort Formula Conditioning Solution, or BOSTON SIMPLICITY Multi-Action Solution in conjunction with *Boston® Liquid Enzymatic Cleaner*.

A five day ocular irritation study was conducted in the rabbit to investigate the ocular irritation and toxicity potential of the *Boston® Liquid Enzymatic Cleaner* used in a lens care regimen employing BOSTON Cleaner and BOSTON Conditioning Solution with BOSTON ES Rigid Gas Permeable Contact Lenses.

A primary ocular irritation test was conducted using extracts from the red screw cap, red bulb cap, blue screw cap, and blue bulb cap packaging components for *Boston® Liquid Enzymatic Cleaner* to determine the potential for any extractable ocular irritants.

The results of these tests demonstrate that the product and packaging components are not toxic.

Microbiology:

Sterility:

Studies carried in accordance with USP 23, 1995, Chapter 95, 1689, were performed to demonstrate the sterility of *Boston® Liquid Enzymatic Cleaner*.

Biostatic Efficacy:

The biostatic activity of *Boston® Liquid Enzymatic Cleaner* was determined using a combination of two test methods. One was the Bacteriostasis Test Method as described in the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1 1997*. The other was the Preservative Efficacy Test Method for Multi-Dose Preserved Contact Lens Care Products, is also described in the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1 1997*.

At the zero time point, separate samples of three lots of *Boston® Liquid Enzyme Cleaner* were each inoculated with one of the five USP-designated microorganisms to a final concentration of approximately 1×10^6 cfu/mL. Test microbes included bacteria (*Staphylococcus aureus*, *Pseudomonas aeruginosa*, and *Eschericia coli*), yeast (*Candida albicans*), and mold (*Aspergillus niger*). Test samples were assayed at 7 and 14 days after inoculation to determine the concentrations of surviving microorganisms. Immediately after the 14-day assay, each test solution was rechallenged with a fresh inoculum of the same species of microorganisms. Test samples were continually assayed every 7 days through 42 days after initial challenge, and were assayed every 2-3 weeks thereafter, up to at least 98 days to establish the 90 day discard date.

Disinfection Efficacy:

The *Boston® Liquid Enzymatic Cleaner*/conditioning solution combination was tested in accordance with the disinfection efficacy requirements in the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care, May 1, 1997 Products*. BOSTON Conditioning Solution, BOSTON ADVANCE Comfort Formula Conditioning Solution and BOSTON SIMPLICITY Multi-Action Solution were tested for disinfection efficacy in combination with *Boston® Liquid Enzymatic Cleaner*.

The results from these tests support that the product has acceptable antimicrobial activity.

Shelf Life:

Expiration dating was established based on the Shelf-life Protocol testing in accord 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*.

Lens/Solution Compatibility:

The compatibility of *Boston® Liquid Enzymatic Cleaner* with silicone acrylate and fluoro silicone acrylate rigid gas permeable contact lenses was determined using a test procedure that is based on the Solution Compatibility Test Protocol found 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.

The results of these tests demonstrate the compatibility of the proposed regimens with silicone acrylate and fluoro silicone acrylate rigid gas permeable contact lenses.

In-Vitro Cleaning:

The cleaning efficacy of *Boston® Liquid Enzymatic Cleaner* dissolved in BOSTON Conditioning Solution, BOSTON ADVANCE Comfort Formula Conditioning Solution and BOSTON SIMPLICITY Multi-Action Solution compared to Alcon OPTI-ZYME Enzymatic Cleaner dissolved in Bausch & Lomb Sensitive Eyes Saline Solution was determined by Image Analysis

Human worn RGP lenses were treated with both *Boston® Liquid Enzymatic Cleaner* and with Alcon OPTI-ZYME. The lenses were evaluated for protein level determination. This type of cleaning evaluation is suggested in the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997.*

The results of these tests demonstrate that the cleaning efficacy of the product is substantially equivalent to the predicate device.

10. CLINICAL:

The clinical study used to support this premarket notification was carried out to determine that the *Boston® Liquid Enzymatic Cleaner* is substantially equivalent in safety and efficacy when compared to the currently marketed Alcon OPTI-ZYME Enzymatic Cleaner, when used with currently marketed silicone acrylate and fluoro-silicone acrylate lens materials.

The study involved six investigational sites and 103 patients (206 eyes) for a period of three months. 69 patients (64 eyes) used *Boston® Liquid Enzymatic Cleaner*, and 32 patients (64 eyes) used marketed Alcon OPTI-ZYME Enzymatic Cleaner.

Of the 103 subjects entered into the study, 95 subjects completed the study. Twelve subjects were discontinued from the study. No subjects were discontinued from the study for adverse reactions. Subjects recruited into the study ranged in age from 18 - 69, with a mean age of 43.2.

Completed and discontinued patients reported consistently good visual acuities with 95.1% of acuities reported for completed eyes at 20/30 or better. During the study the average lens wearing time for completed eyes was between 13.7 and 14.2 hours per day.

11. CONCLUSION:

The results from all non-clinical and clinical studies demonstrate that the *Boston® Liquid Enzymatic Cleaner* is safe, effective, and is substantially equivalent to the predicate device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Douglas J. Fortunato
Director, Regulatory Affairs
Polymer Technology
1400 North Goodman Street
Rochester, NY 14692

NOV 24 1997

Re: K973217
Trade Name: Boston® Liquid Enzymatic Cleaner
Regulatory Class: II
Product Code: 86 LPN
Dated: August 26, 1997
Received: August 27, 1997

Dear Mr. Fortunato:

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

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Indications for Use Statement

510(k) Number (if known): K973217

Device Name: *Boston® Liquid Enzymatic Cleaner*

Indications for Use:

The *Boston® Liquid Enzymatic Cleaner* is indicated for weekly enzymatic cleaning of fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses during simultaneous conditioning (wetting, soaking, and disinfecting) with Original Formula *Boston®* Conditioning Solution, *Boston ADVANCE®* Comfort Formula Conditioning Solution, or *Boston SIMPLICITY®* Multi-Action Solution.

(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 ✓

Myra Smith JS

(Sign-Off)

of Ophthalmic Devices

510(k) Number K973217