

K974466

FEB 19 1998

510(K) SUMMARY

1. **SUBMITTER:**
Company Name: Polymer Technology,
a division of Wilmington Partners, L.P.
Address: 1400 North Goodman Street
Rochester, NY 14692

2. **CONTACT PERSON:**
Address: Douglas J. Fortunato
Manager, Regulatory Affairs
1400 North Goodman Street
Rochester, NY 14692
Telephone No.: (716) 338-5477
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E-mail Address: dfortunato@bausch.com

3. **DEVICE IDENTIFICATION:**
Trade Name: *Boston Advance® Cleaner*
Common Name: contact lens cleaner
Classification Name: Rigid Gas Permeable contact lens care product

4. **CLASSIFICATION NAME AND REFERENCE:**
Class II Ophthalmic Device
21 CFR 886.5925 5918

5. **PREMARKET NOTIFICATION NUMBER:**

6. **INDICATION FOR USE:**
The modified *Boston Advance® Cleaner* is indicated for use to clean fluoro silicone and silicone acrylate rigid gas permeable contact lenses after each removal and before conditioning (wetting, soaking, and disinfecting).

7. **DEVICE DESCRIPTION:**
Boston Advance® Cleaner is a sterile, concentrated, homogeneous surfactant solution containing alky ether sulfate, ether sulfate, ethoxylated alkyl phenol, triquateryary cocoa-based phospholipid, silica gel as cleaning agents, with titanium dioxide.

8. STATEMENT OF EQUIVALENCE:

Boston Advance® Cleaner is substantially equivalent to the currently marketed Boston Advance® Cleaner, approved on May 3, 1990 under PMA, and Boston® Cleaner. The device has the same basic technological characteristics as the predicate devices relative to design, packaging and composition.

9. DESCRIPTION OF SAFETY AND SUBSTANTIAL EQUIVALENCE:

A series of *in-vitro* and *in-vivo* preclinical chemical, toxicological, and microbiological studies were performed to assess the safety and effectiveness of *Boston Advance® 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:

In vitro biological reactivity (Agar Diffusion, USP 23, 1995, Chapter 87, 1698) tests were conducted using Boston IV (silicone acrylate) and Boston ES (fluoro silicone acrylate) Rigid Gas Permeable Contact Lenses treated with a lens care regimen employing BOSTON ADVANCE Comfort Formula Conditioning Solution in conjunction with *Boston Advance® Cleaner*.

The results of these tests demonstrate that the product is not toxic.

Microbiology:

Sterility:

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

The antimicrobial activity of *Boston Advance® Cleaner* was determined using a combination of two test methods. The Bacteriostasis Test Method and the Preservative Efficacy Test Method for Multi-Dose Preserved Contact Lens Care Products. Both methods are described in the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1 1997*.

Biostatic Efficacy:

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 samples were assayed at 7 and 14 days after inoculation to determine the concentrations of surviving 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.

Preservative Efficacy:

After six months of storage at defined temperatures and humidity conditions samples from three lots were tested using the Preservative Efficacy of Multi-Dose Preserved Contact Lens Care Products method. Results demonstrate that the modified *Boston Advance® Cleaner* meets the requirements for multi-dose preserved contact lens care products.

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 Advance® 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 critical micelle concentrations (CMC) of the three surfactants used in the formulation were evaluated. This test is described in *Premarket Notification (510 (k)) Guidance Document for Contact Lens Care Products, May 1, 1997*. The critical micelle concentrations were calculated using the data collected. The concentration of each of the surfactants was found to be above the critical micelle concentration for each of the surfactants.

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

10. CLINICAL:

Purpose

The purpose of this study was to demonstrate that the investigational daily cleaner, the modified *Boston Advance® Cleaner* (test), is substantially equivalent in safety and efficacy when compared to the currently marketed *Boston Advance® Cleaner* (control), which was approved in May 3, 1990 under PMA P890054, when used with currently marketed rigid gas permeable (RGP) contact lens materials on a daily wear basis. These lens materials include silicone acrylate and fluoro-silicone acrylate materials. The study started in April 1997,

concluded in November 1997, and was carried out in accordance with the *Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products, May 1, 1997*.

The study involved 12 investigational sites and 170 patients (340 eyes) for a period of three months. 114 patients (228 eyes) used modified *Boston Advance® Cleaner*, and 54 patients (108 eyes) used marketed *Boston Advance® Cleaner*.

Of the 168 subjects entered into the study, 151 completed the study. Seventeen subjects were discontinued from the study. None of the 17 discontinued patients, Test or Control, were discontinued for safety or efficacy reasons. Subjects recruited into the study ranged in age from 18 - 60 years of age with a mean age of 37.5. There were 132 females and 38 males.

Conclusion

Based on these data, it is concluded that the modified *Boston Advance® Cleaner* (Test), is substantially equivalent in safety and efficacy to the currently marketed *Boston Advance® Cleaner* (Control).

11. CONCLUSION:

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 19 1998

Mr. Douglas J. Fortunato
Manager, Regulatory Affairs
Polymer Technology Corporation
1400 N. Goodman Street
Rochester, NY 14692

Re: K974466
Trade Name: Boston Advance ® Cleaner (new visibility tinted formula)
Regulatory Class: II
Product Code: 86 LPN
Dated: November 25, 1997
Received: November 26, 1997

Dear Mr. Fortunato:

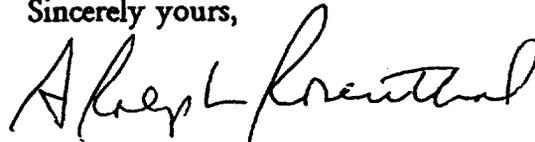
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 at (301) 443-6597.

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,
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1400 North Goodman Street
Rochester, NY 14692-0450

Indications for Use Statement

510(k) Number (if known): K 9 7 4 4 6 6

Device Name: Boston Advance® Cleaner

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

SYO 87

(Division Sign-Off)
Division of Ophthalmic Devices

510(k) Number K 9 7 4 4 6 6