

MAY - 2 2003

K024289

**510 (k) SUMMARY  
SUMMARY OF SAFETY AND EFFECTIVENESS  
FOR**

**Boston SIMPLUS Multi-Action Solution**

**1. Submitter Information**

Polymer Technology  
A Bausch & Lomb company  
1400 North Goodman Street  
Rochester, New York 14609

Contact Person: Jennifer B. Murray  
Global Regulatory Affairs

Telephone Number: 585-338-8460

**2. Device Name**

Classification Name: Rigid Gas Permeable Contact Lens Care Product

Proprietary Name: Boston® SIMPLUS Multi-Action Solution

**3. Predicate Devices**

Boston Simplicity® Multi-Action Solution, Bausch & Lomb ReNu MultiPlus® Multi-Purpose Solution and Alcon Unique pH were selected as the predicate devices for Boston SIMPLUS Multi-Action Solution.

**4. Description of the Device**

Boston SIMPLUS Multi-Action Solution is a sterile, aqueous, buffered solution that contains poloxamine, hydroxyalkylphosphonate, boric acid, sodium borate, sodium chloride, hydroxypropylmethyl cellulose, Glucam and preserved with chlorhexidine gluconate (0.003%), polyaminopropyl biguanide (0.0005%).

5. **Indications for Use**

Boston SIMPLUS Multi-Action Solution is for cleaning, removing protein, rinsing, disinfecting, conditioning, storing and cushioning fluoro silicone acrylate and silicone acrylate rigid gas permeable contact lenses.

6. **Description of Safety and Substantial Equivalence**

A series of preclinical and clinical studies were completed on Boston SIMPLUS Multi-Action Solution. The results indicate that this product is safe, efficacious, and substantially equivalent to the predicate devices identified in Section 3 of this summary.

**Toxicology**

A series of in-vitro biological reactivity tests were performed to determine the toxicity of Boston SIMPLUS Multi-Action Solution.

ISO Agarose Overlay Tests of Boston SIMPLUS Multi-Action Solution, Fluoro Silicone Acrylate Lenses Cycled in Boston SIMPLUS Multi-Action Solution and Silicone Acrylate Lenses Cycled in Boston SIMPLUS Multi-Action Solution were conducted in accordance with the requirements of ISO 10993-5. The negative and positive controls performed as anticipated. The test articles demonstrated no evidence of cell lysis. All test requirements were met.

ISO Ocular Irritation Tests of Boston SIMPLUS Multi-Action Solution, extracts of fluoro silicone acrylate lenses cycled in Boston SIMPLUS Multi-Action Solution and extracts of silicone acrylate lenses cycled in Boston SIMPLUS Multi-Action Solution were conducted in accordance with the requirements of ISO 10993: Biological Evaluation of Medical Devices, Part 10: Tests for Irritation and Sensitization. The test solution did not produce significant ocular irritation. All test requirements were met.

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

**Stability/Sterility**

Stability studies were performed to evaluate the effects of various temperatures on the physical, microbiological and chemical properties of various lots of Boston SIMPLUS Multi-Action Solution. These studies are on-going. To date, all data indicates that the test product meets its specifications.

**Cleaning Studies**

The cleaning efficacy of Boston SIMPLUS Multi-Action Solution was determined by a series of in-vitro studies. In addition, the returned clinical lenses were evaluated for cleanliness.

The Critical Micelle Concentration of the surfactant in Boston SIMPLUS Multi-Action Solution was evaluated and found acceptable.

Testing was performed to determine the cleaning ability of Boston SIMPLUS Multi-Action Solution on rigid gas permeable contact lenses. The first model employed a protein and lipid mixture deposition. The results of this model indicate that the test solution cleans equivalently to or better than the positive and negative controls. A second model employed a tenacious deposition of protein. The results of this model indicate that the test solution cleans better than the positive and negative controls.

Lens compatibility studies were performed to determine the average changes observed in the physical lens parameters of rigid gas permeable contact lenses when subjected to repeated cleaning cycles with Boston SIMPLUS Multi-Action Solution. The physical lens parameters tested within the specifications. The cosmetic appearance of both lens materials tested equivalent to their respected controls.

Lenses returned from the clinical study that were used with either the Test (Boston SIMPLUS Multi-Action Solution) or Control (Boston Simplicity Multi-Action Solution) regimens have been examined by Image Analysis for lens cleanliness and found to be substantially equivalent.

#### Microbiology Studies

A series of studies as provided in the Premarket Notification (510(k)) Guidance Document for Contact Lens Care Products were completed to demonstrate the microbiological efficacy of Boston SIMPLUS Multi-Action Solution.

Microbiology testing included Preservative Efficacy with Rechallenge, Disinfection Efficacy-Stand Alone, Disinfection Efficacy-Stand Alone with Organic Soil and a Regimen Test. All results are satisfactory and indicate that the product meets FDA/ISO requirements.

#### Clinical Studies

A multi-site randomized, controlled clinical study was conducted to evaluate the safety and efficacy of Boston SIMPLUS Multi-Action Solution employing a regimen that requires the user to rub lenses after the disinfection cycle. The Control solution was Boston Simplicity Multi-Action Solution traditional rub and rinse steps.

Patients were instructed to wear their lenses on a daily wear basis with no scheduled replacements and to clean and disinfect them in accordance with the provided directions for use. Evaluations included visual acuity, lens surface characteristics, and physiological response. The safety endpoint of no statistically significant difference in the incidence rate of any Grade 2 or greater slit lamp findings between the Test and Control was satisfied. The efficacy endpoint of statistical equivalence in the proportion of lens visual acuities at the level of 20/40 or better was met.

**Both solutions demonstrated clinically acceptable lens cleanliness. Safety and efficacy were demonstrated. Boston SIMPLUS Multi-Action Solution is substantially equivalent to Boston Simplicity Multi-Action Solution.**

### **Substantial Equivalence**

**Boston SIMPLUS Multi-Action Solution for use with rigid gas permeable contact lenses is substantially equivalent to Boston Simplicity Multi-Action Solution, Bausch & Lomb ReNu Multi-Purpose Solution and Alcon Unique pH Solution.**

**Boston SIMPLUS Multi-Action Solution will be sold in plastic bottles as a sterile solution; each bottle will be marked by a lot number and expiration date.**



MAY - 2 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Bausch & Lomb Incorporated  
c/o Jennifer B. Murray  
Associate Manager  
1400 N. Goodman Street  
Rochester, NY 14609

Re: K024289  
Trade/Device Name: Boston SIMPLUS Multi-Action Solution  
Regulation Number: 21 CFR 886.5918  
Regulation Name: Rigid gas permeable contact lens care products  
Regulatory Class: Class II  
Product Code: MRC  
Dated: April 21, 2003  
Received: April 22, 2003

Dear Ms. Murray:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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, M.D.  
Director  
Division of Ophthalmic and Ear,  
Nose and Throat Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

Polymer Technology  
a Bausch & Lomb company  
1400 North Goodman Street  
Rochester, NY 14609

**Indications for Use Statement**

510(k) Number (if known): K024289

Device Name: Boston® SIMPLUS Multi-Action Solution

**Indications for Use:**

Boston SIMPLUS Multi-Action Solution is indicated for use in cleaning, removing protein, rinsing, disinfecting, conditioning, storing and cushioning 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



\_\_\_\_\_  
(Division Sign-Off)  
Division of Ophthalmic Ear,  
Nose and Throat Devices



510(k) Number K024289