

K962512

JUL 12 1996

BOSTON® Contact Lens Case**Summary of Safety and Effectiveness**

Sponsor/Applicant: Polymer Technology,
a Division of Wilmington Partners L.P.
100 Research Drive
Wilmington, MA 01887

Trade/Proprietary Name: BOSTON® Contact Lens Case

Classification Name: Contact lens case

Common/Usual Name: Contact lens case

Contact: Quality/Regulatory Affairs
(508) 658-6111

Statement of Equivalence: Based on similar designs and on indications for use with rigid gas permeable contact lenses, The BOSTON Contact Lens Case is substantially equivalent to the following marketed product:

BOSTON® Contact Lens Case (K951552)

Device Description : The BOSTON® Contact Lens Case is plastic and double-welled with ridged screw caps on the wells. The interiors of the wells and caps contain elevated ridges to prevent the adherence of rigid gas permeable contact lenses to the surfaces.

Toxicology Testing: In support of this premarket notification information from the following was submitted for review:

Systemic Injection Test
Eye Irritation Test
Cytotoxicity Test

Indications for Use: The BOSTON Contact Lens Case is indicated for disinfection and storage of rigid gas permeable contact lenses.