

MAY - 6 1997

510(k) SUMMARY K970698

SUBMITTED BY:

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

TRADE/PROPRIETARY NAME

BOSTON[®] ES[™] MULTIVISION (enflucocon A) Contact Lens

CLASSIFICATION NAME:

Contact Lens - rigid gas permeable

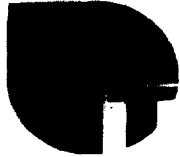
COMMON/USUAL NAME:

Fluoro Silicone Acrylate Rigid Gas Permeable Contact Lens Material

PREMARKET NOTIFICATION NUMBER:

CONTACT PERSON:

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***INDICATIONS FOR USE:***

The BOSTON® MULTIVISION (enflucocon A) Contact Lens is indicated for daily wear for the correction of visual acuity in hyperopic and myopic, not-aphakic and aphakic, presbyopic patients with non-diseased eyes, who exhibit astigmatism of 2.00 diopters or less and can obtain satisfactory visual acuity. The lens provides a nominal functional add of 1.50 diopters. The lens may be disinfected using a chemical disinfecting system only.

STATEMENT OF EQUIVALENCE:

The BOSTON ES MULTIVISION (enflucocon A) contact lens is made of the same material as BOSTON ES (enflucocon A), a daily wear fluoro silicone acrylate contact lens material as cleared under 510(k) Premarket Notification No. K943177. The United States Adopted Name (USAN) enflucocon A is unchanged. Substantial equivalence is also determined by the design equivalence to the BAUSCH & LOMB Occasions™ (polymacon) Visibility Tinted Multifocal Contact Lens as approved under PMA N16-895; and the BOSTON ENVISION aspheric single vision, back surface design as cleared under 510(k) Premarket Notification No. K942365. Equivalence in design is determined by both lens designs being aspheric, in which a series of different radius curves from center to edge of the lens are used to describe the back surface of the lens, and create the 'add' effect for the multifocal power.

DEVICE DESCRIPTION:

The BOSTON ES MULTIVISION (enflucocon A) is an aspheric multifocal rigid gas permeable, fluoro silicone acrylate contact lens for daily wear. The BOSTON ES MULTIVISION (enflucocon A) contact lens provides distance and near vision through the use of its back surface design. The central portion of the lens provides the distance vision; the mid-peripheral portion provides the near vision and the far peripheral portion provides the fitting performance of the lens. The aspheric design is a series of ever increasing radius curves from the center of the lens to the periphery which provides the 'add' power for



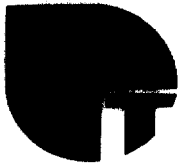
central ellipse for distance vision, a hyperbolic curve in the mid-periphery for the near vision, and a fillet and steeper hyperbolic design in the periphery for the fitting design.

The lens parameters available are:

<i>Chord Diameter:</i>	7.0 to 11.5 mm (to prescription)
<i>Center Thickness:</i>	0.07 to 0.65 mm (varies with power and diameter)
<i>Base Curve:</i>	5.0 to 9.0 mm in 0.01 mm steps
<i>Power:</i>	+20.00 to -20.00 in 0.12 D increments for distance +1.50 D nominal add
<i>Optical Zone:</i>	To prescription

All physical, optical and chemical properties are equivalent to the BOSTON ES (enflucocon A) material as cleared in 510(k) K943177. See attached summary. The physical properties of the subject contact lens are as follows:

<i>Oxygen Permeability:</i>	$31 \times 10^{-11} (\text{cm}^3 \text{O}_2 \cdot \text{cm}) / (\text{cm}^2 \cdot \text{sec} \cdot \text{mmHg})$ @ 35°C (standard deviation=3)
<i>Wetting Angle:</i>	52° ±3
<i>Water Content:</i>	<1% (Gravimetric Method)
<i>Index of Refraction:</i>	1.443±0.003 (Abbe Refractometer)
<i>Light Transmittance:</i>	84.6% at average thickness of 0.15 mm (-3.00)

***CLINICAL:***

The clinical study used to support this premarket notification is the clinical study conducted on the same material in support of the spherical indication for myopia and hyperopia as reported in K943177 approved on August 25, 1994.

The study involved eleven investigational sites and 216 patients (432 eyes) for a period of three months. 217 subjects entered the study and 185 subjects completed the study. Thirty-one 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 to 67, with a mean age of 39.

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.

CONCLUSION:

The results from all non-clinical and clinical studies demonstrate that the BOSTON ES rigid gas permeable contact lens is safe, effective, and performs as well as or better than the predicate device.