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**Summary of Safety and Effectiveness
for the FreeSoft (polymacon) Soft (hydrophilic)
Aspheric Contact Lens**



The material from which the lens will be manufactured is FDA approved polymacon (2-HEMA) which, when fully hydrated, is 38% water. This polymer is the original soft (hydrophilic) contact lens material and has been tested for performance, comfort and oxygen transmissibility since 1972. It is the most widely employed polymer in the contact lens industry. There are over four FDA approved manufacturers of polymacon polymer.

The equipment and processes which Unilens Corp., USA uses to manufacture polymacon lenses are identical to those which are used to manufacture their other hydrophilic lenses.

The FreeSoft (polymacon) Soft (Hydrophilic) Aspheric Contact Lens is an aspheric lens design the same as many other lenses on the market, such as the Unilens 38 (polymacon) Aspheric Contact Lens (510(k) K941836), Ideal Optics PS (polymacon) Aspheric Contact Lens (PMA No. P830012-S003), the Fulfocus (polymacon) Aspheric Contact Lens manufactured by Contact Lens Corporation of America (PMA No. P830006-S005), the Allvue (polymacon) Aspheric Contact Lens manufactured by Salvatori Ophthalmics (PMA No. P840006-S007) and the VX Soft Lens (polymacon) Aspheric Contact Lens manufactured by GBF Contact Lens (PMA No. P780013-S004 approved August 13, 1991).

The FreeSoft (polymacon) Aspheric Contact Lens is a front surface asphere with a base curve consisting of multiple radii. The front asphere creates the most plus power in the center of the lens, with the power becoming more minus towards the periphery. The multiple radii in the base curve produce increased plus power in the lens. This is a similar design as the other aspheric lenses listed above and the Unilens (hefilcon A) Soft (Hydrophilic) Aspheric Contact Lens which has been manufactured at this facility since our approval June 6, 1990 under PMA No. P850002-S005. The lenses have been designed so as to allow about 1 mm movement on the blink. This movement of the lens provides tear exchange to increase the oxygen under the lens and will assist in the removal of corneal metabolic wastes.

It is felt that a lens made of a polymer, such as polymacon, which has been safely used for over 20 years and utilizing an accepted aspheric design which has good movement on the eye and a record of healthy wear, should produce the safest of conditions.

Unilens Corp., USA has been approved to manufacture lenses made of lower water content polymers since October 1985. The major part of our manufacture has been Soft (Hydrophilic) Contact Lenses for Daily Wear. The present application is for a slightly lower water content (38%) polymacon for Daily Wear. Unilens Corp., USA has almost 10 years experience in the manufacture of this type of lens. Our facility was last inspected by the FDA on February 22, 1993.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.