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J. 510(k) SUMMARY
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3. **Date Summary Prepared:** May 1, 1996
4. **Name of Device:**
 - **Trade Name:** Hydrasoft (East)
 - **Common Name:** Soft Contact Lens
 - **Classification Name:** Soft (hydrophilic) Contact Lens
(Per 21 CFR § 886.5925)
5. **Legally Marketed Device:** Hydrasoft^R and Hydrasoft^R Toric
(methafilcon B)
6. **Description of Device:**

The HYDRASOFT (East) (methafilcon B) Soft (hydrophilic) Contact lens is available as a spherical or astigmatic (toric) lens. The lens material, methafilcon B, is a random copolymer of hydroxyethylmethacrylate and methacrylic acid.

When placed on the cornea in its hydrated state the HYDRASOFT (East) Contact Lens act as a refracting medium to focus light rays on the retina.

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7. Intended Use:

The HYDRASOFT (East) lens is intended for use as a daily wear lens for the correction of refractive ametropia (myopic, hyperopic and astigmatism) in aphakic and not-aphakic persons with non-diseased eyes.

8. Technological Characteristics:

The technological characteristics of the HYDRASOFT (East) spherical lens and HYDRASOFT TORIC (East) Lens are the same as the predicate device, Hydrasoft^R and Hydrasoft^R Toric.

9. Summary of Non-Clinical Tests:

Physical and chemical properties testing was performed on lenses made using the alternate manufacturing method and polymerization process as called or in the May 1994 Premarket Notification (510(k)) Guidance Document For Daily Wear Contact Lenses. Water content, light transmittance, refractive index and mechanical properties were tested. Toxicity was determined by the Systemic Injection Test, and Cytotoxicity Test along with company data incorporated by reference to an identical manufacturing process for tetrafilcon A lenses.

10. Conclusion:

The determination of substantial equivalence is based on the results of non-clinical testing. Review of the all test data demonstrates methafilcon B lenses manufactured with the alternate manufacturing method and polymerization process are equivalent to the currently marketed Hydrasoft^R and Hydrasoft^R Toric contact lenses. The Hydrasoft (East) and Hydrasoft Toric (East) contact lenses have the same design, indication and directions for use as the Hydrasoft^R and Hydrasoft^R Toric contact lenses. CooperVision, Inc. concludes, therefore, that the Hydrasoft (East) and Hydrasoft Toric (East) contact lenses are substantially equivalent to the Hydrasoft^R and Hydrasoft^R Toric contact lenses.