



New Device Approvals

Horizon 55 EW and Horizon 55 EW Westint Contact Lenses- P990072

This is a brief overview of information related to FDA's approval to market this product. See the links below to the Summary of Safety and Effectiveness and product labeling for more complete information on this product, its indications for use, and the basis for FDA's approval.

Product Name: Horizon 55 EW and Horizon 55 EW Westint (methafilcon A)
Soft Contact Lenses
Manufacturer: Westcon Contact Lens Co., Inc.,
Address: 611 Eisenhower Street, Grand Junction, CO 81505
Approval Date: August 22, 2000
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990072a.pdf>

What is it? The device is a soft (hydrophilic or water-absorbing) contact lens available in a spherical shape. The lens material is approximately 45% water and 55% methafilcon A (a polymer of hydroxy-ethyl-methacrylate).

How does it work? When placed on the eye, the lens refracts (or bends) light so that it focuses the light rays on the retina (the light-sensitive area in the back of the eye).

When is it used? The lens may be worn for extended periods of from 1 to 7 days, between removals for cleaning and disinfection.

What will it accomplish? The lens corrects conditions where light does not focus properly (refractive error) such as near-sightedness (myopia) and far-sightedness (hyperopia).

When should it not be used? The lens should not be used when an inflammation or infection of the eye is present, or when any eye disease or injury affects the cornea, conjunctiva or eyelids.

Additional information: Summary of Safety and Effectiveness is available at:
<http://www.fda.gov/cdrh/pdf/p990072.html>

(Updated 3/20/01)