# VISTAKON (lenefilcon A) Soft Contact Lenses- P990085

*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.*

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| Product Name: | VISTAKON (lenefilcon A) Soft Contact Lenses |
| Manufacturer: | Vistakon, Division of Johnson & Johnson Vision Care, Inc. |
| Address: | P.O. Box 10157, Jacksonville, FL 32247-0157 |
| Approval Date: | February 16, 2001 |
| Approval Letter: | http://www.fda.gov/cdrh/pdf/p990085a.pdf |

What is it? The device is a soft, hydrophilic (water absorbing), contact lens, available in spherical, rounded (toric) bifocal and rounded bifocal lens designs. The lens material is approximately 55% water and 45 lenefilcon A, (a polymer of hydroxy-ethyl-methacrylate).

How does it work? When placed on the eye, the lens focuses light onto the retina (the light-sensitive area in the back of the eye).

When is it used? The lens is used for daily wear during waking hours. It may also 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), far-sightedness (hyperopia), astigmatism, and long-sightedness or impaired vision accompanying advancing years (presbyopia).

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/p990085.html

(Updated 3/22/01)