



New Device Approvals

CeeOn™ Edge Foldable Intraocular Lens - Model 911A- P990080

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: CeeOn™ Edge Foldable Intraocular Lens - Model 911A
Manufacturer: Pharmacia and Upjohn
Address: 7000 Portage Road, Kalamazoo, Michigan 49001-0199
Approval Date: April 5, 2001
Approval Letter: <http://www.fda.gov/cdrh/pdf/p990080a.pdf>

What is it? The Model 911A is a foldable lens, called an “intraocular lens,” used to replace the natural lens of the eye after it is removed during surgery for cataracts. (A cataract is a clouding of the lens of the eye that makes it hard to see clearly). The lens part of the Model 911A is made of silicone and is held in the eye by plastic loops.

How does it work? The Model 911A is folded before it is placed into the eye, allowing the surgeon to make a smaller cut. Once in place, it gives the patient an ability to see objects far away. A person receiving this lens would still need to wear “reading glasses” for near vision.

When is it used? This foldable lens is implanted to correct vision in persons 60 or older who have had a natural lens removed for the treatment of cataracts.

What will it accomplish? In a U.S. clinical study of the Model 911A used in otherwise healthy patients, most achieved 20/40 or better corrected vision. The percentage of patients who had complications following surgery was similar to that for other implanted lenses.

When should it not be used? The patient and surgeon should consider the potential risks and benefits in deciding whether or not to implant this device. Your doctor may choose not to use this device if there is inflammation/infection in the eye, if removing the cataract was especially difficult, or if there is a defect in the eye that would not allow normal placement of the lens. These warnings are the same as those for other intraocular lenses.

Additional information:

- Summary of Safety and Effectiveness and Labeling are available at: <http://www.fda.gov/cdrh/pdf/990080.html>
- Word on Health, National Institutes of Health: <http://www.nih.gov/news/WordonHealth/jan99/story01.htm>
- U.S. National Library of Medicine: <http://www.nlm.nih.gov/medlineplus/cataract.html>

- American Society of Cataract and Refractive Surgery: <http://www.ascrs.org/eye/eye.html>
- American Academy of Ophthalmology: (search for "intraocular lens" in to get specific information): <http://www.medem.com/search/default.cfm>

(Updated 5/8/01)