

Alcon Laboratories, Inc.
K965185 AcryPak® Folder

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K965185

510(K) SUMMARY

Submitted by:

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Trade Name:	AcryPak® Folder
Common Name	IOL Len Folder
Classification Name	Intraocular Lens Guide, 21 CFR 886.4300

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1. Predicate Device

The legally marketed device(s) to which we are claiming equivalence to is:

1. K913626, Softrans[™] Injector, (STAAR Surgical Company)
2. K903574, ChiroFlex[®] Lens Microsert[®], (Chiron Ophthalmics Inc.)

2. Device Description

The AcryPak[®] Folder is a sterile, single-use IOL folder that allows the user to load and fold ACRYSOFF[®] lenses in 6-12, 3-9, or 4-10 orientation. This lens folder is easy to use and does not require user cleaning and reesterilization. The AcryPak[®] Folder is supplied separately from the IOL.

3. Intended Use of the Device

The intended use of this device is to fold the Alcon ACRYSOFF[®] intraocular lens prior to its insertion into the eye. The AcryPak[®] Folder is used as the folding forceps. A pair of implantation forceps is used to remove the folded lens from the AcryPak[®] Folder for lens implantation.

4. Summary of the Technological Characteristics of the Device

The folding of the ACRYSOFF[®] lens is typically done using conventional metal forceps which requires great dexterity of the user to fold the lens evenly. In addition, folding metal forceps require time to properly clean and re-sterilize for each use.

The AcryPak[®] Folder is a sterile, single use folder molded from polypropylene. The folder allows the user to load the ACRYSOFF[®] lens for 6-12, 3-9, or 4-10 folding. Use of the AcryPak[®] Folder will not affect the incision size, which is determined by the lens and the implantation forceps.

The lens folding function of the AcryPak[®] Folder is equivalent to that of the cartridges of lens injectors used for other types of lenses. However, AcryPak[®] Folders provide the capability of multi-axis lens folding which cartridges do not provide.

5. Summary of the Performance Data

The performance of the AcryPak[®] Folder was tested using low, medium and high diopter ACRYSOFF[®] lenses. The test results demonstrated that the AcryPak[®] Folder folded all the lenses evenly in all three folding orientations. All the test lenses possessed acceptable focal length, resolution, haptic angle, overall length and cosmetic quality after testing.

6. Conclusions

The AcryPak[®] Folder is easy to use, performs reliably, and is effective in folding ACRYSOFF[®] IOLs without compromising the quality of the lens. It is supplied sterile and eliminates the need for user cleaning and reesterilization.