FDA 510(k) Premarket Notification

K965185 ACRYPAK FOLDER

CLEARED

Mar 31, 1997
97 days to decision

K965185 · Product code: **KYB** · Ophthalmic
Source: https://www.510kdatabase.net/k965185/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Guide, Intraocular (KYB)
Date received	Dec 24, 1996
Decision date	Mar 31, 1997
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alcon Laboratories**
Location	Mchenry, IL, US
Contact	MARTIN A KAUFMAN
Website	https://www.alcon.com
510(k) history	47 submissions · 47 cleared · 1976-2007

Alcon Laboratories is a Swiss-American pharmaceutical and medical device company specializing in eye care products. The company maintains operational headquarters in Fort Worth, Texas, with a significant global presence in eye care innovation. Alcon has received FDA 510(k) clearances from total submissions since its first clearance in 1976. The company's regulatory portfolio is dominated by Ophthalmic devices, which account for 74% of all submissions. The latest clearance on record dates to 2007, reflecting the company's historical significance in the medical device regul...