

K970033 MONARCH IOL DELIVERY SYSTEMApr 23, 1997
110 days to decisionK970033 · Product code: **KYB** · Ophthalmic
Source: <https://www.510kdatabase.net/k970033/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Guide, Intraocular (KYB)
Date received	Jan 3, 1997
Decision date	Apr 23, 1997
Days to decision	110 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...
