FDA 510(k) Premarket Notification

K881682 ALCON SITE(R)-COMPATIBLE CASSETTE

CLEARED

Jul 1, 1988
73 days to decision

K881682 · Product code: **KYG** · Ophthalmic
Source: https://www.510kdatabase.net/k881682/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Irrigation, Ocular Surgery (KYG)
Date received	Apr 19, 1988
Decision date	Jul 1, 1988
Days to decision	73 days
Third-party review	No

APPLICANT

Company	**Alcon Laboratories**
Location	Mchenry, IL, US
Contact	REBECCA G WALKERS
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...

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Device record: https://www.510kdatabase.net/k881682/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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