FDA 510(k) Premarket Notification

K971618 ALCON CONTACT LENS CASE

CLEARED

Jul 14, 1997
73 days to decision

K971618 · Product code: **LRX** · Ophthalmic
Source: https://www.510kdatabase.net/k971618/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Case, Contact Lens (LRX)
Date received	May 2, 1997
Decision date	Jul 14, 1997
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Alcon Laboratories**
Location	Mchenry, IL, US
Contact	MICHEAL E PFLEGER
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...