FDA 510(k) Premarket Notification

K880961 ALCON SURGICAL PROCEDURE PACKS

CLEARED

Apr 29, 1988
52 days to decision

K880961 · Product code: **LRO** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k880961/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	General Surgery Tray (LRO)
Date received	Mar 8, 1988
Decision date	Apr 29, 1988
Days to decision	52 days
Third-party review	No

APPLICANT

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