

K062865 SMALL VOLUME SYRINGEAug 23, 2007
332 days to decisionK062865 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k062865/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 25, 2006
Decision date	Aug 23, 2007
Days to decision	332 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Alcon Laboratories
Location	Mchenry, IL, US
Contact	SEAN P GRIFFIN
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...
