FDA 510(k) Premarket Notification

K062500 FLEXPEN NEEDLE

CLEARED

Nov 21, 2006
88 days to decision

K062500 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k062500/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 25, 2006
Decision date	Nov 21, 2006
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Novo Nordisk, Inc.**
Location	Princeton, NJ, US
Contact	RICK SPRING
510(k) history	14 submissions · 14 cleared · 2005-2023