FDA 510(k) Premarket Notification

K090111 FLEXPEN NEEDLE

CLEARED

Feb 1, 2010
381 days to decision

K090111 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k090111/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 16, 2009
Decision date	Feb 1, 2010
Days to decision	381 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