

K090111 FLEXPEN NEEDLEFeb 1, 2010
381 days to decisionK090111 · Product code: **FMI** · General HospitalSource: <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

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