FDA 510(k) Premarket Notification

K123766 NOVOPEN ECHO, A DIAL A DOSE INSULIN DELIVERY PEN

CLEARED

Aug 15, 2013
251 days to decision

K123766 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k123766/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 7, 2012
Decision date	Aug 15, 2013
Days to decision	251 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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