

**K123766 NOVOPEN ECHO, A DIAL A DOSE INSULIN DELIVERY PEN**

Aug 15, 2013  
251 days to decision

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

**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k123766/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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