

**K182387 NovoPen Echo Dial-A-Dose Insulin Delivery Device
(Pen Injector)**Dec 17, 2018
104 days to decisionK182387 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k182387/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Sep 4, 2018
Decision date	Dec 17, 2018
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Novo Nordisk, Inc.
Location	Princeton, NJ, US
Contact	Elizabeth D'Amato
510(k) history	14 submissions · 14 cleared · 2005-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182387/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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