FDA 510(k) Premarket Notification

K162602 NovoPen Echo

CLEARED

Oct 18, 2016
29 days to decision

K162602 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k162602/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Sep 19, 2016
Decision date	Oct 18, 2016
Days to decision	29 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.net
Device record: https://www.510kdatabase.net/k162602/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026