

K210258 NovoFineJun 23, 2021
142 days to decisionK210258 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k210258/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 1, 2021
Decision date	Jun 23, 2021
Days to decision	142 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Novo Nordisk, Inc.
Location	Princeton, NJ, US
Contact	Hiral Palkhiwala Shah
510(k) history	14 submissions · 14 cleared · 2005-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210258/> 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