

**K231255 NovoFine® Plus**Aug 25, 2023  
116 days to decisionK231255 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k231255/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 1, 2023
Decision date	Aug 25, 2023
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Novo Nordisk, Inc.</b>
Location	Princeton, NJ, US
Contact	Hiral Palkhiwala Shah
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/k231255/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 14, 2026