FDA 510(k) Premarket Notification

K210258 NovoFine

CLEARED

Jun 23, 2021
142 days to decision

K210258 · Product code: **FMI** · General Hospital
Source: 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