FDA 510(k) Premarket Notification

K010359 INNOVO

CLEARED

Mar 14, 2001
36 days to decision

K010359 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k010359/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Feb 6, 2001
Decision date	Mar 14, 2001
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Novo Nordisk A/S**
Location	Princeton, NJ, US
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510(k) history	1 submissions · 1 cleared · 2001-2001