FDA 510(k) Premarket Notification

K001572 NEOLUS NEEDLE

CLEARED

Aug 14, 2000
84 days to decision

K001572 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k001572/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 22, 2000
Decision date	Aug 14, 2000
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Terumo Europe N.V.**
Location	Leuven, BE
Contact	M J AERTS
510(k) history	28 submissions · 28 cleared · 1999-2025