FDA 510(k) Premarket Notification

CLEARED

K151398 K-Pack II Needle - 29G x 5/16 Thin Wall

Jun 25, 2015
30 days to decision

K151398 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k151398/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 26, 2015
Decision date	Jun 25, 2015
Days to decision	30 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