FDA 510(k) Premarket Notification

K100946 INTRAVSCULAR ADMINISTRATION SET

CLEARED

Aug 2, 2010
118 days to decision

K100946 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k100946/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Set, Administration, Intravascular (FPA)
Date received	Apr 6, 2010
Decision date	Aug 2, 2010
Days to decision	118 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