FDA 510(k) Premarket Notification

K053413 TERUMO SYRINGE FOR ADMINISTRATION OF UV SENSITIVE MEDICINES

CLEARED

Apr 6, 2006
120 days to decision

K053413 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k053413/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Dec 7, 2005
Decision date	Apr 6, 2006
Days to decision	120 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