

K083514 TERUMO SYRINGE WITH/WITHOUT NEEDLEMay 22, 2009
177 days to decisionK083514 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k083514/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 26, 2008
Decision date	May 22, 2009
Days to decision	177 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083514/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 23, 2026