

**K161606 Syringe with fixed needle - For use only with GONAL-F
Multi-Dose 600 I/U mL FSH**

Feb 10, 2017
245 days to decision

K161606 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k161606/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jun 10, 2016
Decision date	Feb 10, 2017
Days to decision	245 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.net

Device record: <https://www.510kdatabase.net/k161606/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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