

K003571 SERONO FOR USE WITH GONAL-F 1200IU MULTI-DOSE ONLY AT 600IU/ML SYRINGEFeb 12, 2001
84 days to decisionK003571 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k003571/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Syringe, Piston (FMF)
Date received	Nov 20, 2000
Decision date	Feb 12, 2001
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Terumo Medical Corp.
Location	Elkton, MD, US
Contact	BARBARA SMITH
510(k) history	143 submissions · 143 cleared · 1980-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k003571/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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