

**K063613 MODIFICATION TO TERUMO SYRINGE  
WITH/WITHOUT NEEDLE**

Dec 26, 2006  
21 days to decision

K063613 · Product code: **FMF** · General Hospital  
Source: <https://www.510kdatabase.net/k063613/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Syringe, Piston (FMF)
Date received	Dec 5, 2006
Decision date	Dec 26, 2006
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Terumo Medical Corp.</b>
Location	Elkton, MD, US
Contact	SANDI HARTKA
510(k) history	143 submissions · 143 cleared · 1980-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k063613/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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