

K140516 Terumo Pen Injector Needle 34Aug 5, 2014
158 days to decisionK140516 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k140516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 28, 2014
Decision date	Aug 5, 2014
Days to decision	158 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kofu Factory of Terumo Corp.
Location	Nakakoma-Gun, Yamanashi, JP
Contact	PHILLIP LESTER
510(k) history	4 submissions · 4 cleared · 2005-2014

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