

K170276 Safety Blood Collection Device for Single UseDec 11, 2017
315 days to decisionK170276 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k170276/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 30, 2017
Decision date	Dec 11, 2017
Days to decision	315 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gentier Medical (Shanghai), Inc.
Location	Shanghai, CN
Contact	Lenny Cao
510(k) history	5 submissions · 5 cleared · 2017-2022

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