

K080235 SAFETY INFUSION SETApr 24, 2008
85 days to decisionK080235 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k080235/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 30, 2008
Decision date	Apr 24, 2008
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Greiner Bio-One Vacuette North America
Location	Baldwin, MD, US
Contact	JUDITH SMITH
510(k) history	5 submissions · 5 cleared · 2001-2008

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