FDA 510(k) Premarket Notification

K121908 SAFETY INFUSION SET

CLEARED

Jul 25, 2012
26 days to decision

K121908 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k121908/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jun 29, 2012
Decision date	Jul 25, 2012
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Greiner Bio-One North America, Inc.**
Location	Baldwin, MD, US
Contact	JUDITH SMITH
510(k) history	10 submissions · 10 cleared · 2006-2024