K090117 AUTOSAFE-REFLEX SAFETY HUBER INFUSION SET, AUTOSAFE ADVANTAGE SAFETY HUBER INFUSION SET

CLEARED

Sep 29, 2009
251 days to decision

K090117 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k090117/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 21, 2009
Decision date	Sep 29, 2009
Days to decision	251 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Autosafe-Reflex, Inc.**
Location	Alpharetta, GA, US
Contact	JOHN STEPHENS
510(k) history	1 submissions · 1 cleared · 2009-2009