

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

Sep 29, 2009  
251 days to decision

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

**SUBMISSION DETAILS**

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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**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k090117/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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