

**K042917 STAT MEDICAL PEN NEEDLE**Apr 22, 2005  
182 days to decisionK042917 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k042917/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Oct 22, 2004
Decision date	Apr 22, 2005
Days to decision	182 days
Third-party review	Yes
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Emergogroup, Inc.</b>
Location	Clearwater, FL, US
Contact	RENE VAN DE ZANDE
510(k) history	2 submissions · 2 cleared · 2004-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042917/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026