

**K950159 SURESHARP**Apr 14, 1995  
87 days to decisionK950159 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k950159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Jan 17, 1995
Decision date	Apr 14, 1995
Days to decision	87 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Gainor Medical U.S.A., Inc.</b>
Location	Mcdonough, GA, US
Contact	WILLIAM C TAYLOR
510(k) history	2 submissions · 2 cleared · 1995-1995

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