

**K934435 CAP-STIK**Jul 14, 1995  
690 days to decisionK934435 · Product code: **FMI** · General Hospital  
Source: <https://www.510kdatabase.net/k934435/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Aug 23, 1993
Decision date	Jul 14, 1995
Days to decision	690 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Mcshane Medical, Inc.</b>
Location	Deer Park, TX, US
510(k) history	1 submissions · 1 cleared · 1995-1995

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k934435/>; 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 July 6, 2026