

**K000455 GETTIG GUARD**Apr 19, 2000  
68 days to decisionK000455 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k000455/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Feb 11, 2000
Decision date	Apr 19, 2000
Days to decision	68 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Gettig Pharmaceutical Instrument Co.</b>
Location	Great Neck, NY, US
Contact	JAMES A BENZ
510(k) history	5 submissions · 5 cleared · 1997-2004

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000455/> 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 2, 2026