

**K052725 PROTECTOR NEEDLE SHEATH PROP**Dec 28, 2005  
90 days to decisionK052725 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k052725/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	Sep 29, 2005
Decision date	Dec 28, 2005
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Certol International, LLC</b>
Location	Boulder, CO, US
Contact	LEWIS WARD
510(k) history	1 submissions · 1 cleared · 2005-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052725/> 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 1, 2026