

**K050664 SPOR-TEST PA BIOLOGICAL INDICATOR KIT**Apr 7, 2005  
23 days to decisionK050664 · Product code: **FRC** · General Hospital  
Source: <https://www.510kdatabase.net/k050664/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Indicator, Biological Sterilization Process (FRC)
Date received	Mar 15, 2005
Decision date	Apr 7, 2005
Days to decision	23 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Getinge USA, Inc.</b>
Location	Rochester, NY, US
Contact	BARD SMITH
510(k) history	4 submissions · 4 cleared · 2003-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050664/> 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