

**K122625 GETINGE 800HC- SERIES STEAM STERILIZER**May 22, 2013  
267 days to decisionK122625 · Product code: **FLE** · General Hospital  
Source: <https://www.510kdatabase.net/k122625/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Aug 28, 2012
Decision date	May 22, 2013
Days to decision	267 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Getinge Sourcing, LLC</b>
Location	Rochester, NY, US
Contact	BARB SMITH
510(k) history	7 submissions · 7 cleared · 2007-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122625/> 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 June 2, 2026