

**K103504 GETINGE 400HC/500HC SERIES STEAM STERILIZER**Mar 16, 2011  
110 days to decisionK103504 · Product code: **FLE** · General Hospital  
Source: <https://www.510kdatabase.net/k103504/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sterilizer, Steam (FLE)
Date received	Nov 26, 2010
Decision date	Mar 16, 2011
Days to decision	110 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/k103504/> 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