

**K162540 INNOVANCE(r) Heparin Reagents, INNOVANCE(r) Heparin Calibrator, INNOVANCE(r) Heparin UF and Heparin LMW Controls**Aug 22, 2017  
344 days to decisionK162540 · Product code: **KFF** · Hematology  
Source: <https://www.510kdatabase.net/k162540/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Sep 12, 2016
Decision date	Aug 22, 2017
Days to decision	344 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Siemens Healthcare Diagnostics Prodcets GmbH</b>
Location	Marburg, DE
Contact	ROSE T MARINELLI
510(k) history	1 submissions · 1 cleared · 2017-2017

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162540/> 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 May 28, 2026