

**K010455 ROTACHROM HEPARIN AND STA -ROTACHROM HEPARIN**Jun 7, 2001  
129 days to decisionK010455 · Product code: **KFF** · Hematology  
Source: <https://www.510kdatabase.net/k010455/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Jan 29, 2001
Decision date	Jun 7, 2001
Days to decision	129 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Diagnostica-Stago</b>
Location	Parispany, NJ, US
Contact	ANDREW LOC B LE
510(k) history	3 submissions · 3 cleared · 2001-2016

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k010455/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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