

K013637 ACTICHROME HEPARIN (ANTI-FIIA)Apr 16, 2002
162 days to decisionK013637 · Product code: **KFF** · Hematology
Source: <https://www.510kdatabase.net/k013637/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Nov 5, 2001
Decision date	Apr 16, 2002
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Diagnostica, Inc.
Location	Greenwich, CT, US
Contact	JOHN BERRYMAN
510(k) history	10 submissions · 10 cleared · 1994-2008

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