

K943516 ROTACHROM HBPM/LMWH TEST KITAug 31, 1995
406 days to decisionK943516 · Product code: **KFF** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Jul 21, 1994
Decision date	Aug 31, 1995
Days to decision	406 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Bioproducts Co.
Location	Parsippany, NJ, US
Contact	ANDREW LOC B LE
510(k) history	79 submissions · 75 cleared · 1985-1998

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