

K972209 SPECTROLYSE HEPARIN (ANTI-IIA)Aug 12, 1997
62 days to decisionK972209 · Product code: **KFF** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Jun 11, 1997
Decision date	Aug 12, 1997
Days to decision	62 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Medical Diagnostic Technologies, Inc.
Location	Augusta, GA, US
Contact	MICHAEL D BICK
510(k) history	57 submissions · 57 cleared · 1985-2006

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