

K965076 MDA HEPARIN ANTI-X ASSAYMar 18, 1997
89 days to decisionK965076 · Product code: **KFF** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Dec 19, 1996
Decision date	Mar 18, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Organon Teknika Corp.
Location	Mchenry, IL, US
Contact	RON SANYAL
510(k) history	130 submissions · 129 cleared · 1980-2000

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