

**K923499 SPECTROLYSE HEPARIN KIT**Jan 27, 1994  
561 days to decisionK923499 · Product code: **KFF** · Hematology  
Source: <https://www.510kdatabase.net/k923499/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Jul 15, 1992
Decision date	Jan 27, 1994
Days to decision	561 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Biopool AB</b>
Location	Ontario, L7I 6b8, CA
Contact	ANDERW L CERSKUS
510(k) history	13 submissions · 12 cleared · 1990-1995

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