K993519 RAPIDPOINT ACCENT, MODEL 2000, RAPIDPOINT COAG HEPARIN TITRATION TEST, RAPIDPOINT COAG PROTAMINE RESPONSE TEST

CLEARED

Jan 14, 2000
88 days to decision

K993519 · Product code: **JOX** · Hematology
Source: https://www.510kdatabase.net/k993519/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Heparin, Automated (JOX)
Date received	Oct 18, 1999
Decision date	Jan 14, 2000
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Cardiovascular Diagnostics, Inc.**
Location	Raleigh, NC, US
Contact	PETER SCOTT
510(k) history	13 submissions · 13 cleared · 1995-2002