

K013078 ACTALYKE MINI ACTIVATED CLOTTING TIME TEST SYSTEM, MODEL 5750/5752Jan 10, 2002
118 days to decisionK013078 · Product code: **JBP** · Hematology
Source: <https://www.510kdatabase.net/k013078/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Whole Blood Clotting Time (JBP)
Date received	Sep 14, 2001
Decision date	Jan 10, 2002
Days to decision	118 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	PATRICIA FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013078/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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