

**K020914 ACTALYKE XL ACTIVATED CLOTTING TIME
ANALYZER, MODEL 5770**May 23, 2002
63 days to decisionK020914 · Product code: **JBP** · Hematology
Source: <https://www.510kdatabase.net/k020914/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Whole Blood Clotting Time (JBP)
Date received	Mar 21, 2002
Decision date	May 23, 2002
Days to decision	63 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

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