

**K964609 ACTALYKE ACTIVATED CLOTTING TIME TEST
SYSTEM/CLOTTING TIME TUBES/WHOLE BLOOD QC
KIT/ACTALYKE ELECTRONIC CLOTTING TUBE**Mar 6, 1997
108 days to decisionK964609 · Product code: **JBP** · Hematology
Source: <https://www.510kdatabase.net/k964609/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Activated Whole Blood Clotting Time (JBP)
Date received	Nov 18, 1996
Decision date	Mar 6, 1997
Days to decision	108 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Array Medical, Inc.
Location	Bridgewater, NJ, US
Contact	PATRICIA E BONNESS
510(k) history	3 submissions · 3 cleared · 1997-1999

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