

K934070 TINA-QUANT HEMOGLOBIN A1COct 11, 1994
417 days to decisionK934070 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k934070/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Aug 20, 1993
Decision date	Oct 11, 1994
Days to decision	417 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
Contact	JOHN D STEVENS
510(k) history	340 submissions · 340 cleared · 1976-1999

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