

K974491 ACCU-CHEK A1C HEMOGLOBIN TESTMay 13, 1998
166 days to decisionK974491 · Product code: **LCP** · Hematology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Nov 28, 1997
Decision date	May 13, 1998
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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