

**K952337 ROCHE UNIMATE 3/UNIMATE 5 HBA1C, HBA1C
CALBRATOR, HBA1C CONTROLS N & P**Feb 9, 1996
266 days to decisionK952337 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k952337/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 19, 1995
Decision date	Feb 9, 1996
Days to decision	266 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	CAROL L KRIEGER
510(k) history	296 submissions · 296 cleared · 1983-1999

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