

K940971 AMES DCA 2000 HEMOGLOBIN ALC CONTROLSJul 19, 1994
139 days to decisionK940971 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k940971/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Mar 2, 1994
Decision date	Jul 19, 1994
Days to decision	139 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Heraeus Kulzer, Inc.
Location	Elkhart, IN, US
Contact	ROSANNE M SAVOL
510(k) history	145 submissions · 145 cleared · 1988-2009

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