

K896830 OPTIMATE HEMOGLOBIN A1CSep 11, 1990
281 days to decisionK896830 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k896830/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Dec 4, 1989
Decision date	Sep 11, 1990
Days to decision	281 days
Third-party review	No

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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