

K941616 VARIANT TOTAL GHB PROGRAMApr 14, 1995
375 days to decisionK941616 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k941616/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Apr 4, 1994
Decision date	Apr 14, 1995
Days to decision	375 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bio-Rad
Location	Mchenry, IL, US
Contact	JOHN W NELSON
Website	http://www.bio-rad.com
510(k) history	319 submissions · 319 cleared · 1976-2017

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