

K935613 RADIAS MONOCLONAL HBA 1C ASSAYApr 5, 1994
134 days to decisionK935613 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k935613/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Nov 22, 1993
Decision date	Apr 5, 1994
Days to decision	134 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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