

K973365 AIC - CHEK (HBAIC-I)Jun 15, 1998
280 days to decisionK973365 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k973365/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Sep 8, 1997
Decision date	Jun 15, 1998
Days to decision	280 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Express-Med, Inc.
Location	Columbus, OH, US
Contact	D. ALAN SCANTLAND
510(k) history	1 submissions · 1 cleared · 1998-1998

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