

K971919 EZCHEK/HBA BLOOD COLLECTION KITSep 5, 1997
105 days to decisionK971919 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k971919/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 23, 1997
Decision date	Sep 5, 1997
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Flexsite Diagnostics, Inc.
Location	Washington, DC, US
Contact	DONALD R STONE
510(k) history	2 submissions · 2 cleared · 1997-2000

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