

**K031539 HEMOGLOBIN A1C REAGENT SET**Aug 6, 2003  
82 days to decisionK031539 · Product code: **LCP** · Chemistry  
Source: <https://www.510kdatabase.net/k031539/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	May 16, 2003
Decision date	Aug 6, 2003
Days to decision	82 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Pointe Scientific, Inc.,</b>
Location	Mchenry, IL, US
Contact	WILLIAM F WALTERS
510(k) history	74 submissions · 74 cleared · 1981-2007

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