

**K811567 ORTHO\* BI-LEVEL ASSAYED GLYCOH. CONTR. S**Sep 16, 1981  
104 days to decisionK811567 · Product code: **LCP** · Hematology  
Source: <https://www.510kdatabase.net/k811567/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Glycosylated Hemoglobin (LCP)
Date received	Jun 4, 1981
Decision date	Sep 16, 1981
Days to decision	104 days
Third-party review	No

**APPLICANT**

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Company	<b>Ortho Diagnostic Systems, Inc.</b>
Location	Carpinteria, CA, US
510(k) history	126 submissions · 126 cleared · 1981-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k811567/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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