

**K810475 HELENA HEMOGLOBIN F CONTROLS**Mar 26, 1981  
31 days to decisionK810475 · Product code: **KQI** · Hematology  
Source: <https://www.510kdatabase.net/k810475/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Fetal Hemoglobin (KQI)
Date received	Feb 23, 1981
Decision date	Mar 26, 1981
Days to decision	31 days
Third-party review	No

**APPLICANT**

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Company	<b>Helena Laboratories</b>
Location	Mchenry, IL, US
510(k) history	280 submissions · 280 cleared · 1978-2013

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

Device record: <https://www.510kdatabase.net/k810475/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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