

**K803016 HELENA HEMESPEC II TOTAL HEMOGLOBIN MET.**Dec 30, 1980  
32 days to decisionK803016 · Product code: **GKR** · Hematology  
Source: <https://www.510kdatabase.net/k803016/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Hemoglobin, Automated (GKR)
Date received	Nov 28, 1980
Decision date	Dec 30, 1980
Days to decision	32 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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Device record: <https://www.510kdatabase.net/k803016/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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