

**K050014 HEMONIR TM**May 5, 2005  
122 days to decisionK050014 · Product code: **GLY** · Hematology  
Source: <https://www.510kdatabase.net/k050014/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oximeter To Measure Hemoglobin (GLY)
Date received	Jan 3, 2005
Decision date	May 5, 2005
Days to decision	122 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Nir Diagnostics, Inc.</b>
Location	North Attleboro, MA, US
Contact	CYNTHIA A SINCLAIR
510(k) history	1 submissions · 1 cleared · 2005-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k050014/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026