

**K123316 HEINE OMEGA 500**Feb 26, 2013  
124 days to decisionK123316 · Product code: **HLI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k123316/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Oct 25, 2012
Decision date	Feb 26, 2013
Days to decision	124 days
Third-party review	Yes
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Heine Optotechnik GmbH &amp; Co. KG</b>
Location	Hamburg, DE
Contact	JORG RONNAU
510(k) history	7 submissions · 7 cleared · 2010-2015

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123316/> 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 4, 2026