

**K133758 CENTERVUE MACULAR INTEGRITY ASSESSMENT**Apr 23, 2014  
133 days to decisionK133758 · Product code: **HLI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k133758/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Dec 11, 2013
Decision date	Apr 23, 2014
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Centervue S.P.A.</b>
Location	Padova, IT
Contact	ROGER GRAY
510(k) history	13 submissions · 13 cleared · 2010-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k133758/> 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 May 25, 2026