

**K843596 NIDEK-BINOCULAR INDIRECT OPHTHALMOSCOPE**Feb 15, 1985  
156 days to decisionK843596 · Product code: **HLI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k843596/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Sep 12, 1984
Decision date	Feb 15, 1985
Days to decision	156 days
Third-party review	No

**APPLICANT**

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Company	<b>Nidek, Inc.</b>
Location	Mchenry, IL, US
Contact	THERESA M NEWTON
510(k) history	77 submissions · 77 cleared · 1983-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k843596/>; 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 19, 2026