

**K083387 MODIFICATION TO KOWA NONMYD ALPHA-DIII**Jan 16, 2009  
60 days to decisionK083387 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k083387/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Nov 17, 2008
Decision date	Jan 16, 2009
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kowa Co. , Ltd.</b>
Location	Rockville, MD, US
Contact	AKIHIRO FUJITA
510(k) history	16 submissions · 16 cleared · 2005-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083387/> 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 7, 2026