

**K091098 KOWAGENESIS-DF**Aug 7, 2009  
113 days to decisionK091098 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k091098/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Apr 16, 2009
Decision date	Aug 7, 2009
Days to decision	113 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 GUJITA
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/k091098/> 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