

**K191945 KOWA nonmyd 8**Sep 10, 2019  
50 days to decisionK191945 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k191945/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jul 22, 2019
Decision date	Sep 10, 2019
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kowa Company , Ltd.</b>
Location	Chofu-Shi, JP
Contact	Nariaki Morita
510(k) history	3 submissions · 3 cleared · 2019-2022

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191945/> 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