

K101628 KOWA NONMYD WXJan 26, 2011
230 days to decisionK101628 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k101628/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Jun 10, 2010
Decision date	Jan 26, 2011
Days to decision	230 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Kowa Co. , Ltd.
Location	Rockville, MD, US
Contact	SATOHICO TAKANASHI
510(k) history	16 submissions · 16 cleared · 2005-2014

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