

K080681 KOWA GENESIS-DApr 4, 2008
25 days to decisionK080681 · Product code: **HKI** · Ophthalmic
Source: <https://www.510kdatabase.net/k080681/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Mar 10, 2008
Decision date	Apr 4, 2008
Days to decision	25 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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