

K091039 KOWA, FM-600, MODEL LSS50Aug 7, 2009
116 days to decisionK091039 · Product code: **MYC** · Ophthalmic
Source: <https://www.510kdatabase.net/k091039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Laser, Scanning (MYC)
Date received	Apr 13, 2009
Decision date	Aug 7, 2009
Days to decision	116 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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