

K190056 KOWA VK-2sFeb 12, 2019
32 days to decisionK190056 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k190056/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Jan 11, 2019
Decision date	Feb 12, 2019
Days to decision	32 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kowa Co. Ltd. Chofu
Location	Chofu City, JP
Contact	Rinji Kondo
510(k) history	1 submissions · 1 cleared · 2019-2019

REGULATORY CONSULTANT

Consulting firm	Ora, Inc.
Contact	Ryan Bouchard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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