

K181345 Image Filing Software NAVIS-EXJul 19, 2018
59 days to decisionK181345 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k181345/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	May 21, 2018
Decision date	Jul 19, 2018
Days to decision	59 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Nidek Co., Ltd.
Location	Lake Forest, CA, US
Contact	Yoneji Mizuno
510(k) history	20 submissions · 19 cleared · 2001-2023

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