

K181501 AfinaNov 2, 2018
148 days to decisionK181501 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k181501/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Jun 7, 2018
Decision date	Nov 2, 2018
Days to decision	148 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Neurovision Imaging, LLC
Location	Sacramento, CA, US
Contact	Pepe Davis
510(k) history	1 submissions · 1 cleared · 2018-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181501/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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