

K211715 RetinAI DiscoveryApr 28, 2022
329 days to decisionK211715 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k211715/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Jun 3, 2021
Decision date	Apr 28, 2022
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Retinai Medical AG
Location	Bern, CH
Contact	Enisa Dresevic
510(k) history	1 submissions · 1 cleared · 2022-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211715/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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