FDA 510(k) Premarket Notification

K211715 RetinAI Discovery

CLEARED

Apr 28, 2022
329 days to decision

K211715 · 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