

K200275 OVision Imaging SystemMar 3, 2020
28 days to decisionK200275 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k200275/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Feb 4, 2020
Decision date	Mar 3, 2020
Days to decision	28 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ophthalmic Labs, Inc.
Location	Milton, MA, US
Contact	Matthew Carnevale
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Third Party Review Group, LLC
Contact	DAVE YUNGVIRT

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

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