

K210396 Harmony Referral SystemSep 13, 2021
215 days to decisionK210396 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k210396/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Feb 10, 2021
Decision date	Sep 13, 2021
Days to decision	215 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Topcon Healthcare Solutions EMEA Oy
Location	Oulu, FI
Contact	Ramya Sundaram
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	O'Connell Regulatory Consultants, Inc.
Contact	Maureen O'Connell

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

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