

**K253893 Harmony Referral System with Harmony OCT Viewer
(Octave)**Jun 4, 2026
182 days to decisionK253893 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k253893/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Dec 4, 2025
Decision date	Jun 4, 2026
Days to decision	182 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	Tobias Schwarz
510(k) history	2 submissions · 2 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	Topcon Healthcare, Inc.
Contact	Ian Boland

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k253893/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 9, 2026