

K232828 IMAGEnet6 Ophthalmic Data SystemMar 1, 2024
170 days to decisionK232828 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k232828/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Sep 13, 2023
Decision date	Mar 1, 2024
Days to decision	170 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Topcon Corporation
Location	North Reading, MA, US
Contact	Ryota Kitawaki
Website	http://www.topcon.com
510(k) history	13 submissions · 13 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	Orasi Consulting
Contact	Lena Sattler

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/k232828/> 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 May 14, 2026