

K182376 HarmonySep 28, 2018
28 days to decisionK182376 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k182376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Aug 31, 2018
Decision date	Sep 28, 2018
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Topcon Medical Systems, Inc.
Location	Paramus, NJ, US
Contact	James Lorkowski
510(k) history	11 submissions · 11 cleared · 2003-2018

REGULATORY CONSULTANT

Consulting firm	O&apos;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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