

**K200954 Glaucoma Module**Aug 3, 2020  
116 days to decisionK200954 · Product code: **NFJ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k200954/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Apr 9, 2020
Decision date	Aug 3, 2020
Days to decision	116 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Topcon Healthcare Solutions, Inc.</b>
Location	Oakland, NJ, US
Contact	Ramya Sundaram
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>O&amp;apos;Connell Regulatory Consultants, Inc.</b>
Contact	Maureen O&apos;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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