

**K200385 CONTINUUM PACS**Mar 16, 2020  
27 days to decisionK200385 · Product code: **NFJ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k200385/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Feb 18, 2020
Decision date	Mar 16, 2020
Days to decision	27 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Integrated Ophthalmic Systems, Inc.</b>
Location	Woburn, MA, US
Contact	Matthew Carnevale
510(k) history	1 submissions · 1 cleared · 2020-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>Accelerated Device Approval Services</b>
Contact	Rafael Aguila

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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