

**K213527 FORUM**Aug 15, 2022  
284 days to decisionK213527 · Product code: **NFJ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k213527/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Nov 4, 2021
Decision date	Aug 15, 2022
Days to decision	284 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carl Zeiss Meditec, AG</b>
Location	Dublin, CA, US
Contact	Stefan Wimmer
Website	<a href="http://www.zeiss.com/meditec-ag/en_de/home.html">http://www.zeiss.com/meditec-ag/en_de/home.html</a>
510(k) history	45 submissions · 44 cleared · 2004-2025

Carl Zeiss Meditec, AG is a global medical device manufacturer specializing in innovative solutions for ophthalmology and microsurgery. The company operates with a manufacturing facility in Dublin, US, and delivers diagnostic and surgical instruments to healthcare professionals worldwide. The company has received FDA 510(k) clearances from total submissions since 2004. Ophthalmic devices represent the dominant category, accounting for 71% of submissions. The latest clearance in 2025 reflects continued regulatory activity and product innovation in this specialized field. C...

**REGULATORY CONSULTANT**

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Consulting firm	<b>Carl Zeiss Meditec USA, Inc.</b>
Contact	Maria Golovina

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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