

**K123464 CALLISTO EYE**Mar 5, 2013  
116 days to decisionK123464 · Product code: **NFJ** · Ophthalmic  
Source: <https://www.510kdatabase.net/k123464/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Nov 9, 2012
Decision date	Mar 5, 2013
Days to decision	116 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carl Zeiss Meditec, AG</b>
Location	Dublin, CA, US
Contact	JUDY BRIMACOMBE
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...

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