

K240215 BLUE 400Jun 28, 2024
154 days to decisionK240215 · Product code: **QFX** · Neurology
Source: <https://www.510kdatabase.net/k240215/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diagnostic Neurosurgical Microscope Filter (QFX)
Date received	Jan 26, 2024
Decision date	Jun 28, 2024
Days to decision	154 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	BLUE 400 S

APPLICANT

Company	Carl Zeiss Meditec, AG
Location	Dublin, CA, US
Contact	Seitz Anke
Website	http://www.zeiss.com/meditec-ag/en_de/home.html
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

Consulting firm	Carl Zeiss Meditec, Inc.
Contact	Chaitali Gawde

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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Device record: <https://www.510kdatabase.net/k240215/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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