

K211346 BLUE 400Jul 22, 2022
445 days to decisionK211346 · Product code: **QFX** · Neurology
Source: <https://www.510kdatabase.net/k211346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Diagnostic Neurosurgical Microscope Filter (QFX)
Date received	May 3, 2021
Decision date	Jul 22, 2022
Days to decision	445 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Meditec, AG
Location	Dublin, CA, US
Contact	Hans-Joachim Miesner
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	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)
