FDA 510(k) Premarket Notification

K260694 ZEISS CLINIC 360

CLEARED

Jul 17, 2026
136 days to decision

K260694 · Product code: **NFJ** · Ophthalmic
Source: https://www.510kdatabase.net/k260694/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Mar 3, 2026
Decision date	Jul 17, 2026
Days to decision	136 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	Todd Milholland
Website	http://www.zeiss.com/meditec-ag/en_de/home.html
510(k) history	46 submissions · 45 cleared · 2004-2026

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 USA, Inc.**
Contact	Marysa Lyew

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov