FDA 510(k) Premarket Notification

K141297 FORUM GLAUCOMA WORKPLACE

CLEARED

Oct 3, 2014
137 days to decision

K141297 · Product code: **NFJ** · Ophthalmic
Source: https://www.510kdatabase.net/k141297/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	May 19, 2014
Decision date	Oct 3, 2014
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carl Zeiss Meditec, AG**
Location	Dublin, CA, US
Contact	MANDY AMBRECHT
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k141297/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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