

K090439 FORUMMar 25, 2009
33 days to decisionK090439 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k090439/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Feb 20, 2009
Decision date	Mar 25, 2009
Days to decision	33 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Meditec, Inc.
Location	San Diego, CA, US
Contact	KENT W JONES
Website	https://www.zeiss.com/meditec
510(k) history	29 submissions · 29 cleared · 1993-2025

Carl Zeiss Meditec, Inc. is a global medical device manufacturer specializing in innovative solutions for ophthalmology and microsurgery. The company operates with a manufacturing facility in San Diego, California, and is part of the ZEISS Group, a leader in optical and optoelectronic technologies since 1846. The company maintains a strong FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. Ophthalmic devices represent the dominant focus, accounting for approximately 86% of submissions. Carl Zeiss Meditec has been active in FDA clearances since...
