FDA 510(k) Premarket Notification

K093521 GDXPRO

CLEARED

Nov 25, 2009
12 days to decision

K093521 · Product code: **MYC** · Ophthalmic
Source: https://www.510kdatabase.net/k093521/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Laser, Scanning (MYC)
Date received	Nov 13, 2009
Decision date	Nov 25, 2009
Days to decision	12 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Carl Zeiss Meditec, Inc.**
Location	San Diego, CA, US
Contact	JUDY A BRIMACOMBE
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...