FDA 510(k) Premarket Notification

CLEARED

K030433 STRATUSOCT WITH RNFL NORMATIVE DATABASE

May 1, 2003
80 days to decision

K030433 · Product code: **HLI** · Ophthalmic
Source: https://www.510kdatabase.net/k030433/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Feb 10, 2003
Decision date	May 1, 2003
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Carl Zeiss Meditec, Inc.**
Location	San Diego, CA, US
Contact	R. MICHAEL CROMPTON
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...