

K161194 PLEX Elite 9000 SS-OCTOct 26, 2016
182 days to decisionK161194 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k161194/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Apr 27, 2016
Decision date	Oct 26, 2016
Days to decision	182 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Meditec, Inc.
Location	San Diego, CA, US
Contact	CHRISTINE DUNBAR
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...

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