

**K181534 CIRRUS HD-OCT**Feb 15, 2019  
249 days to decisionK181534 · Product code: **OBO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k181534/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Jun 11, 2018
Decision date	Feb 15, 2019
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Carl Zeiss Meditec, Inc.</b>
Location	San Diego, CA, US
Contact	Mandy Ambrecht
Website	<a href="https://www.zeiss.com/meditec">https://www.zeiss.com/meditec</a>
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...