

K222200 CIRRUS HD-OCTApr 13, 2023
262 days to decisionK222200 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k222200/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Jul 25, 2022
Decision date	Apr 13, 2023
Days to decision	262 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Carl Zeiss Meditec, Inc.
Location	San Diego, CA, US
Contact	Vidita Desai
510(k) history	29 submissions · 29 cleared · 1993-2025

REGULATORY CONSULTANT

Consulting firm	Carl Zeiss Meditec USA, Inc.
Contact	Tanesha Bland

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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