FDA 510(k) Premarket Notification

K222200 CIRRUS HD-OCT

CLEARED

Apr 13, 2023
262 days to decision

K222200 · 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