FDA 510(k) Premarket Notification

K233933 CIRRUS™ HD-OCT Model 6000

CLEARED

May 17, 2024
155 days to decision

K233933 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k233933/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Dec 14, 2023
Decision date	May 17, 2024
Days to decision	155 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