FDA 510(k) Premarket Notification

K223557 SPECTRALIS HRA+OCT and variants

CLEARED

Oct 20, 2023
329 days to decision

K223557 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k223557/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Nov 25, 2022
Decision date	Oct 20, 2023
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Heidelberg Engineering GmbH**
Location	Heidelberg, DE
Contact	Arianna Schoess Vargas
510(k) history	16 submissions · 16 cleared · 2011-2025

REGULATORY CONSULTANT

Consulting firm	**Orasi Consulting, LLC**
Contact	Lena Sattler

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