FDA 510(k) Premarket Notification

CLEARED

K250868 SPECTRALIS HRA+OCT and variants

May 12, 2025
49 days to decision

K250868 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k250868/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Mar 24, 2025
Decision date	May 12, 2025
Days to decision	49 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

CLINICAL EVIDENCE - NCT04604002

Evaluation of Additional Heidelberg Engineering SPECTRALIS With OCT Angiography Module (OCTA Module) Scan Types

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	86 patients (actual)
Study sites	1 site
Condition studied	Retinal Vascular; Normal Eyes
Study type	Observational
Completion date	Jan 4, 2022
Sponsor	Heidelberg Engineering GmbH (Industry)

Primary outcome

Image quality score

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04604002