

K253837 SPECTRALIS HRA+OCT and variantsMay 7, 2026
157 days to decisionK253837 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k253837/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Dec 1, 2025
Decision date	May 7, 2026
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	SPECTRALIS with Flex Module

APPLICANT

Company	Heidelberg Engineering GmbH
Location	Heidelberg, DE
Contact	Arianna Schoess Vargas
510(k) history	17 submissions · 17 cleared · 2011-2026

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](https://accessdata.fda.gov)**CLINICAL EVIDENCE - NCT03903588****The Heidelberg Engineering SPECTRALIS Macular Precision and Agreement Study**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	86 patients (actual)
Study sites	1 site
Condition studied	Retinal Layer Separation
Study type	Observational
Completion date	Sep 12, 2019
Sponsor	Heidelberg Engineering GmbH (Industry)

Primary outcome**Retinal Layer Thickness**Source: [ClinicalTrials.gov](https://clinicaltrials.gov) / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT03903588