FDA 510(k) Premarket Notification

K241163 SPECTRALIS with Flex Module

CLEARED

Oct 11, 2024
168 days to decision

K241163 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k241163/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Apr 26, 2024
Decision date	Oct 11, 2024
Days to decision	168 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 - NCT04661124

Evaluation of the Heidelberg Engineering SPECTRALIS With Flex Module for In-vivo Imaging in the Supine Position

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	88 patients (actual)
Study sites	1 site
Condition studied	Retinal Disease; Healthy Eyes
Study type	Observational
Completion date	Apr 22, 2024
Sponsor	Heidelberg Engineering GmbH (Industry)

Primary outcome

The image quality grade of the acquired images as determined by an independent reading center

Secondary outcome

Adverse events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04661124