FDA 510(k) Premarket Notification

K211817 Anterion

CLEARED

Nov 5, 2021
147 days to decision

K211817 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k211817/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Jun 11, 2021
Decision date	Nov 5, 2021
Days to decision	147 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 - NCT04068818

The Heidelberg Engineering ANTERION Imaging Agreement Study

Status	Completed - *No results published to ClinicalTrials.gov*
Enrollment	87 patients (actual)
Study sites	1 site
Condition studied	Eye Abnormalities; Normal Eyes
Study type	Observational
Completion date	Apr 27, 2021
Sponsor	Heidelberg Engineering GmbH (Industry)

Primary outcome

Image quality

Secondary outcome

Adverse Events

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT04068818