

**K181594 Spectralis HRA+OCT and variants with OCT
Angiography Module**Sep 13, 2018
87 days to decisionK181594 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k181594/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Jun 18, 2018
Decision date	Sep 13, 2018
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181594/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026