

K182569 Spectralis HRA+OCT and variants with High Magnification ModuleOct 18, 2018
30 days to decisionK182569 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k182569/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tomography, Optical Coherence (OBO)
Date received	Sep 18, 2018
Decision date	Oct 18, 2018
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182569/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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