

K172649 Spectralis HRA + OCT and variants, Spectralis FA+OCT, Spectralis ICGA+OCT, Spectralis OCT Blue Peak, Spectralis OCT with MulticolorNov 1, 2017
57 days to decisionK172649 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k172649/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tomography, Optical Coherence (OBO)
Date received	Sep 5, 2017
Decision date	Nov 1, 2017
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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