

**K173648 Spectralis HRA + OCT and variants**Aug 30, 2018  
276 days to decisionK173648 · Product code: **OBO** · Ophthalmic  
Source: <https://www.510kdatabase.net/k173648/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Nov 27, 2017
Decision date	Aug 30, 2018
Days to decision	276 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k173648/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 25, 2026