

K192391 Spectralis HRA+OCT and VariantsSep 26, 2019
23 days to decisionK192391 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k192391/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tomography, Optical Coherence (OBO)
Date received	Sep 3, 2019
Decision date	Sep 26, 2019
Days to decision	23 days
Third-party review	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

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