

K162783 EnFocus 2300, EnFocus 4400Dec 9, 2016
67 days to decisionK162783 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k162783/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tomography, Optical Coherence (OBO)
Date received	Oct 3, 2016
Decision date	Dec 9, 2016
Days to decision	67 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bioptigen, Inc.
Location	Washington, DC, US
Contact	Ravi Kommineni
510(k) history	4 submissions · 4 cleared · 2006-2016

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