

**K113759 AVAIRA (ENFILCON A) CONTACT LENS**Apr 3, 2012  
104 days to decisionK113759 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k113759/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Dec 21, 2011
Decision date	Apr 3, 2012
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>CooperVision, Inc.</b>
Location	Southampton, GB
Contact	KARIN GASTINEAU
Website	<a href="https://www.coopervision.com">https://www.coopervision.com</a>
510(k) history	97 submissions · 94 cleared · 1978-2024

CooperVision, Inc. is a contact lens manufacturer based in Southampton, GB. The company specializes in ophthalmic devices for vision correction. CooperVision has received FDA 510(k) clearances from total submissions since its first clearance in 1978. Ophthalmic devices represent 88% of the company's regulatory submissions. The company remains active, with its latest FDA 510(k) clearance in 2024. Recent cleared devices include daily disposable contact lenses in spheric, toric, and multifocal designs. Notable product families include MyDay, Clariti 1 day, Biofinity, and Ava...

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