

K113245 AVAIRA AVAIRA TORIC AVAIRA MULTIFOCALDec 2, 2011
30 days to decisionK113245 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k113245/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Lenses, Soft Contact, Daily Wear (LPL) |
| Date received | Nov 2, 2011 |
| Decision date | Dec 2, 2011 |
| Days to decision | 30 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | CooperVision, Inc. |
| Location | Southampton, GB |
| Contact | GWEN SHARP |
| Website | https://www.coopervision.com |
| 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...
