

**K861565 SERIES TEN THOUSAND COMPACT**Jul 11, 1986  
77 days to decisionK861565 · Product code: **HQE** · Ophthalmic  
Source: <https://www.510kdatabase.net/k861565/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                            |
| Submission type       | Traditional   |
| Device classification | Instrument, Vitreous Aspiration And Cutting, Ac-powered (HQE) |
| Date received         | Apr 25, 1986  |
| Decision date         | Jul 11, 1986  |
| Days to decision      | 77 days   |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>CooperVision, Inc.</b>   |
| Location       | Southampton, GB   |
| Contact        | DAVID W KRAPF   |
| 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k861565/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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