

**K853070 COOPER VISION SYSTEM VI U/S MODULE**Aug 20, 1985  
29 days to decisionK853070 · Product code: **HQC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k853070/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Jul 22, 1985
Decision date	Aug 20, 1985
Days to decision	29 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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