

K842757 ULTRASCAN DIGITAL BJan 9, 1985
177 days to decisionK842757 · Product code: IYO · Radiology
Source: <https://www.510kdatabase.net/k842757/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Imaging, Pulsed Echo, Ultrasonic (IYO)
Date received	Jul 16, 1984
Decision date	Jan 9, 1985
Days to decision	177 days
Third-party review	No

APPLICANT

Company	CooperVision, Inc.
Location	Southampton, GB
Contact	DOUGLASS G ALLEN
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...
