

K830011 VFS 1000/SCREENING FUNCTION ANALYZERJan 17, 1983
14 days to decisionK830011 · Product code: **HOX** · Ophthalmic
Source: <https://www.510kdatabase.net/k830011/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Chart, Visual Acuity (HOX)
Date received	Jan 3, 1983
Decision date	Jan 17, 1983
Days to decision	14 days
Third-party review	No

APPLICANT

Company	CooperVision, Inc.
Location	Southampton, GB
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 spherical, toric, and multifocal designs. Notable product families include MyDay, Clariti 1 day, Biofinity, and Ava...
