

**K962185 HYDRASOFT (EAST) AND HYDRASOFT TORIC(EAST)
(METHAFILCON B) DAILY WEAR SOFT HYDROPHILIC
CONTACT LENS**Dec 17, 1996
194 days to decisionK962185 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k962185/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jun 6, 1996
Decision date	Dec 17, 1996
Days to decision	194 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CooperVision, Inc.
Location	Southampton, GB
Contact	BERNARD HALLATT
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...
