

K041138 LEO COLORS, LEO ASPHERIC COLORS, LEO TORIC COLORSJul 23, 2004
84 days to decisionK041138 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k041138/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Apr 30, 2004
Decision date	Jul 23, 2004
Days to decision	84 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	CooperVision, Inc.
Location	Southampton, GB
Contact	BONNIE J TSYMBAL
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...

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Device record: <https://www.510kdatabase.net/k041138/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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