

K842814 PERMALID LINER PAKAug 1, 1985
379 days to decision

K842814 · Ophthalmic

Source: <https://www.510kdatabase.net/k842814/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - SN
Submission type	Traditional
Date received	Jul 18, 1984
Decision date	Aug 1, 1985
Days to decision	379 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...

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Device record: <https://www.510kdatabase.net/k842814/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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