

K042824 FREQUENCY 38 AND SILVER 07 (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSNov 16, 2004
35 days to decisionK042824 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k042824/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Oct 12, 2004
Decision date	Nov 16, 2004
Days to decision	35 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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