FDA 510(k) Premarket Notification

K032873 PROCLEAR COMPATIBLES MULTIFOCAL

CLEARED

Nov 7, 2003
53 days to decision

K032873 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k032873/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Sep 15, 2003
Decision date	Nov 7, 2003
Days to decision	53 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**CooperVision, Inc.**
Location	Southampton, GB
Contact	LISA HAHN
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...