FDA 510(k) Premarket Notification

K190965 MyDay

CLEARED

Apr 29, 2019
17 days to decision

K190965 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k190965/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Apr 12, 2019
Decision date	Apr 29, 2019
Days to decision	17 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**CooperVision, Inc.**
Location	Southampton, GB
Contact	Marie Dutton
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...