

K191763 MyDay (Stenfilcon A) ASPHERE, MyDay (Stenfilcon A) TORIC, MyDay (Stenfilcon A) MULTIFOCAL, MyDay (Stenfilcon A) MULTIFOCAL TORICMar 23, 2020
266 days to decisionK191763 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k191763/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jul 1, 2019
Decision date	Mar 23, 2020
Days to decision	266 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...