FDA 510(k) Premarket Notification

K812433 LENSINE EXTRA STRENGTH CLEANER

CLEARED

Sep 21, 1981
27 days to decision

K812433 · Product code: **HPX** · Ophthalmic
Source: https://www.510kdatabase.net/k812433/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lens, Contact (polymethylmethacrylate) (HPX)
Date received	Aug 25, 1981
Decision date	Sep 21, 1981
Days to decision	27 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 spheric, toric, and multifocal designs. Notable product families include MyDay, Clariti 1 day, Biofinity, and Ava...