FDA 510(k) Premarket Notification

K851203 R PAK

CLEARED

Jul 23, 1985
119 days to decision

K851203 · Product code: **LFL** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k851203/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Ultrasonic Surgical (LFL)
Date received	Mar 26, 1985
Decision date	Jul 23, 1985
Days to decision	119 days
Third-party review	No

APPLICANT

Company	**CooperVision, Inc.**
Location	Southampton, GB
Contact	DAVID W KRAPP
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...