FDA 510(k) Premarket Notification

K872214 COOPER SURG ASPIRATION CANNULA/CUSTOM CONVEN PAKS

CLEARED

Aug 17, 1987
69 days to decision

K872214 · Product code: **GEA** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k872214/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cannula, Surgical, General & Plastic Surgery (GEA)
Date received	Jun 9, 1987
Decision date	Aug 17, 1987
Days to decision	69 days
Third-party review	No

APPLICANT

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