

K833783 DISPOS. I/A & IRRIGATION HANDPIECESMar 5, 1984
129 days to decisionK833783 · Product code: **HQC** · Ophthalmic
Source: <https://www.510kdatabase.net/k833783/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Phacofragmentation (HQC)
Date received	Oct 28, 1983
Decision date	Mar 5, 1984
Days to decision	129 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 spherical, toric, and multifocal designs. Notable product families include MyDay, Clariti 1 day, Biofinity, and Ava...
