

K843915 MINI-HALO CO2 LASER SYSTEMMay 10, 1985
218 days to decisionK843915 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k843915/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 4, 1984
Decision date	May 10, 1985
Days to decision	218 days
Third-party review	No

APPLICANT

Company	CooperVision, Inc.
Location	Southampton, GB
Contact	DOUGLAS G ALLEN
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...

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Device record: <https://www.510kdatabase.net/k843915/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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