FDA 510(k) Premarket Notification

# K854949 MODEL 9500 ARGON, KRYPTON & DYE SURGICAL LASER SYS

**CLEARED**

Feb 4, 1986
56 days to decision

K854949 · Product code: **HQF** · Ophthalmic
Source: https://www.510kdatabase.net/k854949/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Laser, Ophthalmic (HQF) |
| Date received | Dec 10, 1985 |
| Decision date | Feb 4, 1986 |
| Days to decision | 56 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **CooperVision, Inc.** |
| Location | Southampton, GB |
| Contact | CHARLES L ROSE |
| 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...