

**K830821 MICRO-MITT**Apr 27, 1983  
43 days to decisionK830821 · Product code: **FXP** · General Hospital  
Source: <https://www.510kdatabase.net/k830821/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cover, Shoe, Operating-room (FXP)
Date received	Mar 15, 1983
Decision date	Apr 27, 1983
Days to decision	43 days
Third-party review	No

**APPLICANT**

---

Company	<b>CooperVision, Inc.</b>
Location	Southampton, GB
Website	<a href="https://www.coopervision.com">https://www.coopervision.com</a>
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...

---