

K003376 WELCH ALLYN 11800 OPHTHALMOSCOPEJan 25, 2001
87 days to decisionK003376 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k003376/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Oct 30, 2000
Decision date	Jan 25, 2001
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Welch Allyn, Inc.
Location	McHenry, IL, US
Contact	COLIN WOLFF
Website	http://www.welchallyn.com/
510(k) history	111 submissions · 111 cleared · 1977-2025

Welch Allyn, Inc. is a medical device manufacturer based in McHenry, US. The company specializes in patient monitoring and diagnostic equipment for healthcare settings. Welch Allyn has maintained a strong FDA 510(k) regulatory record since 1977. The company has received FDA 510(k) clearances from total submissions. Cardiovascular monitoring devices represent the dominant category in recent clearances, including the Connex vital signs monitor series and central station systems. The company's latest clearance in 2025 demonstrates continued regulatory activity and product in...
