FDA 510(k) Premarket Notification

K780628 HALOGEN EXAM. LITE #48400

CLEARED

Jun 6, 1978
50 days to decision

K780628 · Product code: **KZF** · General Hospital
Source: https://www.510kdatabase.net/k780628/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Medical Examination, Ac Powered (KZF)
Date received	Apr 17, 1978
Decision date	Jun 6, 1978
Days to decision	50 days
Third-party review	No

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
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...