FDA 510(k) Premarket Notification

CLEARED

K050074 12-LEAD RESTING ELECTROCARDIOGRAPH, MODELS CP100 & CP200

Mar 22, 2005
69 days to decision

K050074 · Product code: **DPS** · Cardiovascular
Source: https://www.510kdatabase.net/k050074/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Electrocardiograph (DPS)
Date received	Jan 12, 2005
Decision date	Mar 22, 2005
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
Contact	CHRISTOPHER KLACZYKN
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...