

**K052158 WELCH ALLYN CARDIOPERFECT WORKSTATION
VERSION 1.5.0 SOFTWARE**Sep 8, 2005
30 days to decisionK052158 · Product code: **BZG** · Anesthesiology
Source: <https://www.510kdatabase.net/k052158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Spirometer, Diagnostic (BZG)
Date received	Aug 9, 2005
Decision date	Sep 8, 2005
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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Device record: <https://www.510kdatabase.net/k052158/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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