

**K132808 VITAL SIGNS MONITOR, CONNEX VITAL SIGNS MONITOR**Nov 20, 2013  
70 days to decisionK132808 · Product code: **MWI** · Cardiovascular  
Source: <https://www.510kdatabase.net/k132808/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Monitor, Physiological, Patient (without Arrhythmia Detection Or Alarms) (MWI)
Date received	Sep 11, 2013
Decision date	Nov 20, 2013
Days to decision	70 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Welch Allyn, Inc.</b>
Location	Mchenry, IL, US
Contact	KEVIN CROSSEN
Website	<a href="http://www.welchallyn.com/">http://www.welchallyn.com/</a>
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...