

**K101680 WELCH ALLYN SPOT VITAL SIGNS LXI MODEL 45000  
SERIES**Jul 9, 2010  
24 days to decisionK101680 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k101680/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 15, 2010
Decision date	Jul 9, 2010
Days to decision	24 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Welch Allyn, Inc.</b>
Location	Mchenry, IL, US
Contact	HUY DOAN
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...