FDA 510(k) Premarket Notification

CLEARED

K191013 Welch Allyn Diagnostic Cardiology Suite 2.X.X with Spirometry option

Sep 10, 2019
146 days to decision

K191013 · Product code: **BZG** · Anesthesiology
Source: https://www.510kdatabase.net/k191013/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Spirometer, Diagnostic (BZG)
Date received	Apr 17, 2019
Decision date	Sep 10, 2019
Days to decision	146 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
Contact	Megan Pellenz
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...