FDA 510(k) Premarket Notification

CLEARED

K120774 ACUITY CENTRAL MONITORING STATION OR ACUITY CENTRAL MONITORING SYSTEM, MOBILE ACUITY LT, MOBILE ACUITY, MOBILE LT

Apr 10, 2012
27 days to decision

K120774 · Product code: **DSI** · Cardiovascular
Source: https://www.510kdatabase.net/k120774/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Detector And Alarm, Arrhythmia (DSI)
Date received	Mar 14, 2012
Decision date	Apr 10, 2012
Days to decision	27 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
Contact	KEVIN CROSSEN
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...