FDA 510(k) Premarket Notification

CLEARED

K012455 WELCH ALLYN DURASHOCK BLOOD PRESSURE SYSTEM

Aug 17, 2001
16 days to decision

K012455 · Product code: **DXQ** · Cardiovascular
Source: https://www.510kdatabase.net/k012455/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Blood Pressure Cuff (DXQ)
Date received	Aug 1, 2001
Decision date	Aug 17, 2001
Days to decision	16 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
Contact	DAVID A YOUNG
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...