FDA 510(k) Premarket Notification

CLEARED

K053381 WELCH ALLYN CONNEX VITAL SOLUTIONS SOFTWARE

Jun 15, 2006
192 days to decision

K053381 · Product code: **DQA** · Anesthesiology
Source: https://www.510kdatabase.net/k053381/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Oximeter (DQA)
Date received	Dec 5, 2005
Decision date	Jun 15, 2006
Days to decision	192 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
Contact	CHRIS KLACZYK
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...