FDA 510(k) Premarket Notification

K984033 ATLAS MONITOR

CLEARED

Jul 8, 1999
238 days to decision

K984033 · Product code: **DRT** · Cardiovascular
Source: https://www.510kdatabase.net/k984033/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Monitor, Cardiac (incl. Cardiotachometer & Rate Alarm) (DRT)
Date received	Nov 12, 1998
Decision date	Jul 8, 1999
Days to decision	238 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
Contact	ZORAN I PSENICNKI
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...