

K861516 WELCH ALLYN TYMPANOMETERJun 10, 1986
48 days to decisionK861516 · Product code: **ETY** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k861516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tester, Auditory Impedance (ETY)
Date received	Apr 23, 1986
Decision date	Jun 10, 1986
Days to decision	48 days
Third-party review	No

APPLICANT

Company	Welch Allyn, Inc.
Location	Mchenry, IL, US
Contact	ROBERT W BECKER
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...
