

K884218 AUDIOSCOPE 3 MODEL 23300 ACCESSORIESMar 10, 1989
155 days to decisionK884218 · Product code: **EWO** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k884218/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Audiometer (EWO)
Date received	Oct 6, 1988
Decision date	Mar 10, 1989
Days to decision	155 days
Third-party review	No

APPLICANT

Company	Welch Allyn, Inc.
Location	Mchenry, IL, US
Contact	JOHN WATKINS
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...
