FDA 510(k) Premarket Notification

K955043 WELCH ALLYN BI-OTOSCOPE

CLEARED

Nov 14, 1995
11 days to decision

K955043 · Product code: **ERA** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k955043/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Nov 3, 1995
Decision date	Nov 14, 1995
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
Contact	COLIN WOLFF
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...