

**K943916 VIDEOTOSCOPE**Aug 25, 1994  
14 days to decisionK943916 · Product code: **ERA** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k943916/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Otoscope (ERA)
Date received	Aug 11, 1994
Decision date	Aug 25, 1994
Days to decision	14 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Welch Allyn, Inc.</b>
Location	Mchenry, IL, US
Contact	SCOTT P GUCCIARDI
Website	<a href="http://www.welchallyn.com/">http://www.welchallyn.com/</a>
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...

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