

K033870 IMAGE MANAGEMENT SYSTEMMar 12, 2004
91 days to decisionK033870 · Product code: **HEX** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k033870/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colposcope (and Colpomicroscope) (HEX)
Date received	Dec 12, 2003
Decision date	Mar 12, 2004
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Welch Allyn, Inc.
Location	McHenry, IL, US
Contact	DAVID KLEMENTOWSKI
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...

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