

**K941272 KLEENSPEC**Aug 2, 1994  
139 days to decisionK941272 · Product code: **HIB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k941272/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Mar 16, 1994
Decision date	Aug 2, 1994
Days to decision	139 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Welch Allyn, Inc.</b>
Location	Mchenry, IL, US
Contact	LAWRENCE E MOROCCO
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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