

K120743 SPECULUM, VAGINAL, NONMETALMar 23, 2012
11 days to decisionK120743 · Product code: **HIB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k120743/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Mar 12, 2012
Decision date	Mar 23, 2012
Days to decision	11 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Welch Allyn, Inc.
Location	Mchenry, IL, US
Contact	KEVIN CROSSEN
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...
