

**K070964 KLEENSPEC SINGLE USE VAGINAL SPECULUM AND
790 SERIES CORDLESS ILLUMINATION SYSTEM**May 18, 2007
43 days to decisionK070964 · Product code: **HIB** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k070964/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Speculum, Vaginal, Nonmetal (HIB)
Date received	Apr 5, 2007
Decision date	May 18, 2007
Days to decision	43 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Welch Allyn, Inc.
Location	Mchenry, IL, US
Contact	CHRIS HORACEK
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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Device record: <https://www.510kdatabase.net/k070964/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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