

K770291 SIGMOIDOSCOPE, DISPOSABLE, MODEL #53125Feb 18, 1977
4 days to decisionK770291 · Product code: **FAM** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k770291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Sigmoidoscope And Accessories, Flexible/rigid (FAM)
Date received	Feb 14, 1977
Decision date	Feb 18, 1977
Days to decision	4 days
Third-party review	No

APPLICANT

Company	Welch Allyn, Inc.
Location	Mchenry, IL, US
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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