

K801247 CCD ENDOSCOPE AND ATTACHMENTS

Jul 28, 1980
61 days to decision

K801247 · Product code: **GCP** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k801247/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscope, Ac-powered And Accessories (GCP)
Date received	May 28, 1980
Decision date	Jul 28, 1980
Days to decision	61 days
Third-party review	No
Combination product	No
PCCP authorized	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...