FDA 510(k) Premarket Notification

K920103 EPISCOPE, MODEL 47300

CLEARED

Apr 28, 1992
110 days to decision

K920103 · Product code: **KZF** · General Hospital
Source: https://www.510kdatabase.net/k920103/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Medical Examination, Ac Powered (KZF)
Date received	Jan 9, 1992
Decision date	Apr 28, 1992
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Welch Allyn, Inc.**
Location	Mchenry, IL, US
Contact	JOHN WATKINS
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...