

**K181016 Welch Allyn RetinaVue Network REF 901108 PACS
Medical Image System**

Jul 16, 2018
90 days to decision

K181016 · Product code: **NFJ** · Ophthalmic
Source: <https://www.510kdatabase.net/k181016/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Image Management, Ophthalmic (NFJ)
Date received	Apr 17, 2018
Decision date	Jul 16, 2018
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Welch Allyn, Inc.
Location	Mchenry, IL, US
Contact	Megan Pellenz
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...