

**K223381 iExaminer System with Panoptic Plus**Mar 15, 2023  
128 days to decisionK223381 · Product code: **HKI** · Ophthalmic  
Source: <https://www.510kdatabase.net/k223381/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Nov 7, 2022
Decision date	Mar 15, 2023
Days to decision	128 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Welch Allyn, Inc.</b>
Location	Mchenry, IL, US
Contact	Jeffrey E. Thompson
Website	<a href="http://www.welchallyn.com/">http://www.welchallyn.com/</a>
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...