

**K250415 G0 Blood Pressure Monitoring System (G0)**Jul 2, 2025  
139 days to decisionK250415 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k250415/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 13, 2025
Decision date	Jul 2, 2025
Days to decision	139 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Aktiia SA</b>
Location	Neuchatel, CH
Contact	Neil Puri
510(k) history	1 submissions · 1 cleared · 2025-2025

**CLINICAL EVIDENCE - NCT06565780****Evaluation of the Performance and Safety of the Aktiia Spot-check Optical Blood Pressure Monitoring Device At Wrist Against Double Auscultation**

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Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	140 patients (actual)
Study sites	1 site
Condition studied	Hypertension
Primary purpose	Other
Study type	Interventional
Study design	Single group
Masking	Open label
Completion date	Jan 10, 2025
Sponsor	Aktiia SA (Industry)

**Primary outcome**

Blood pressure mean value of differences

**Secondary outcome**

Heart rate root-mean-square error

Source: ClinicalTrials.gov / U.S. National Library of Medicine - [clinicaltrials.gov/study/NCT06565780](https://clinicaltrials.gov/study/NCT06565780)