

K251113 iHealth Compare Wireless Blood Pressure Monitor(BP-300C)

Aug 4, 2025
115 days to decision

K251113 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k251113/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 11, 2025
Decision date	Aug 4, 2025
Days to decision	115 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	iHealth Compare Pro Wireless Blood Pressure Monitor(BP-300CV);iHealth Compare S Wireless Blood Pressure Monitor(BP-300V);iHealth Wireless Blood Pressure Monitor(BPX1);iHealth Blood Pressure Monitor(KD-595);iHealth Track Pro Connected Blood Pressure Monitor(KN-550LT);Semi Automatic Blood Pressure Monitor(KD-388N);Arm Blood Pressure Monitor(KD-553);Arm Blood Pressure Monitor(KD-557BR);Arm Blood Pressure Monitor(KD-558);Arm Blood Pr

APPLICANT

Company	Andon Health Co, Ltd.
Location	Tiajin, CN
Contact	Liu Yi
510(k) history	92 submissions · 92 cleared · 2008-2025

CLINICAL EVIDENCE - NCT05551845

Blood Pressure Monitor Clinical Test (Cuff Range: 15-24,20-34,30-44,22-42?)

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	90 patients (actual)
Study sites	1 site
Condition studied	Blood Pressure
Study type	Observational
Completion date	Mar 1, 2022
Sponsor	Andon Health Co., Ltd (Industry)

Primary outcome

blood pressure monitor accuracy

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05551845