

K241590 Arm Blood Pressure Monitor (XY-B01, XY-B02, XY-B03, XY-B05, XY-B07, XY-B08, XY-B09)

Feb 3, 2025
245 days to decision

K241590 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k241590/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 3, 2024
Decision date	Feb 3, 2025
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Xinyu Electronic and Technology Co., Ltd.
Location	Zhongshan, CN
Contact	Rita Long
510(k) history	2 submissions · 2 cleared · 2025-2025

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k241590/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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