

K232621 Blood pressure monitorNov 22, 2023
85 days to decisionK232621 · Product code: **DXN** · CardiovascularSource: <https://www.510kdatabase.net/k232621/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Aug 29, 2023
Decision date	Nov 22, 2023
Days to decision	85 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Guangdong Transtek Medical Electronics Co., Ltd.
Location	Chengdu, Sichuan, CN
Contact	Jerry Fan
510(k) history	17 submissions · 17 cleared · 2013-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k232621/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 13, 2026