FDA 510(k) Premarket Notification

K232621 Blood pressure monitor

CLEARED

Nov 22, 2023
85 days to decision

K232621 · Product code: **DXN** · Cardiovascular
Source: 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