FDA 510(k) Premarket Notification

K220676 Blood Pressure Monitor

CLEARED

Aug 29, 2022
174 days to decision

K220676 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k220676/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Mar 8, 2022
Decision date	Aug 29, 2022
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.**
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Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov