FDA 510(k) Premarket Notification

K202891 Blood Pressure Monitor

CLEARED

Mar 9, 2021
162 days to decision

K202891 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k202891/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 28, 2020
Decision date	Mar 9, 2021
Days to decision	162 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	Endless Chan
510(k) history	17 submissions · 17 cleared · 2013-2025

REGULATORY CONSULTANT

Consulting firm	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Kevin Wang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov