

**K202891 Blood Pressure Monitor**Mar 9, 2021  
162 days to decisionK202891 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k202891/>**SUBMISSION DETAILS**

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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**

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Company	<b>Guangdong Transtek Medical Electronics Co., Ltd.</b>
Location	Chengdu, Sichuan, CN
Contact	Endless Chan
510(k) history	17 submissions · 17 cleared · 2013-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Chonconn Medical Device Consulting Co., Ltd.</b>
Contact	Kevin Wang

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

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k202891/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 24, 2026