

K223291 Electronic Blood Pressure MonitorJun 14, 2023
231 days to decisionK223291 · Product code: **DXN** · CardiovascularSource: <https://www.510kdatabase.net/k223291/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Oct 26, 2022
Decision date	Jun 14, 2023
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Pango Medical Electronics Co., Ltd.
Location	Shenzhen, CN
Contact	Xiaoyun Yang
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	Mid-Link Consulting Co, Ltd.
Contact	Diana Hong

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k223291/> 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 25, 2026