

K253133 Wrist Blood Pressure Monitor (BPM-W1VL)Feb 13, 2026
141 days to decisionK253133 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k253133/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 25, 2025
Decision date	Feb 13, 2026
Days to decision	141 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Imdk Medical Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Yuan Xia
510(k) history	6 submissions · 6 cleared · 2018-2026

REGULATORY CONSULTANT

Consulting firm	Qimmiq Medical Consulting Service Co., Ltd.
Contact	Yijie You

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/k253133/> 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 13, 2026