

**K231367 Wrist Electronic Blood Pressure Monitor(Model FC-BP200, FC-BP201, FC-BP210,FC-BP211, FC-BP220, FC-BP221)**Sep 18, 2023  
130 days to decisionK231367 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231367/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	May 11, 2023
Decision date	Sep 18, 2023
Days to decision	130 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Finicare Co., Ltd.</b>
Location	Shenzhen, CN
Contact	Chao Li
510(k) history	6 submissions · 6 cleared · 2019-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shanghai Truthful Information Technology Co., Ltd.</b>
Contact	Boyle 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](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k231367/>; 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 25, 2026