FDA 510(k) Premarket Notification

CLEARED

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 decision

K231367 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k231367/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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