FDA 510(k) Premarket Notification

CLEARED

K220113 Upper Arm Electronic Blood Pressure Monitor(Model FC-BP100,FC-BP101,FC-BP102,FC-BP110,FC-BP111,FC-BP112)

May 31, 2022
137 days to decision

K220113 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k220113/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jan 14, 2022
Decision date	May 31, 2022
Days to decision	137 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