FDA 510(k) Premarket Notification

CLEARED

K252769 Upper Arm Electronic Blood Pressure Monitor (FC-BP107, FC-BP123, FC-BP125, FC-BP126, FC-BP127, FC-BP116)

Oct 2, 2025
30 days to decision

K252769 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k252769/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 2, 2025
Decision date	Oct 2, 2025
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Finicare Co., Ltd.**
Location	Shenzhen, CN
Contact	Li Chao
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