FDA 510(k) Premarket Notification

K221040 Electronic Sphygmomanometers, Model: X1, X2, X5, X6, X7,X8, X11)

CLEARED

Aug 31, 2022
146 days to decision

K221040 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k221040/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 7, 2022
Decision date	Aug 31, 2022
Days to decision	146 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Jiangxi Aicare Medical Technology Co., Ltd.**
Location	Fuzhou, CN
Contact	Lizhu Xiao
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug and Medical Consulting Technical Service Group**
Contact	Bing Huang

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