FDA 510(k) Premarket Notification

CLEARED

K220886 Upper Arm Type Blood Pressure Monitor

Jul 27, 2022
121 days to decision

K220886 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k220886/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Mar 28, 2022
Decision date	Jul 27, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Jamr Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Luo Fusheng
510(k) history	6 submissions · 6 cleared · 2020-2025

REGULATORY CONSULTANT

Consulting firm	**Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.**
Contact	Reanny Wang

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