FDA 510(k) Premarket Notification

K221212 Upper Arm Blood Pressure Monitor

CLEARED

Aug 26, 2022
121 days to decision

K221212 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k221212/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Apr 27, 2022
Decision date	Aug 26, 2022
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Shenzhen Yolanda Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Xuejun Wang
510(k) history	3 submissions · 3 cleared · 2022-2023

REGULATORY CONSULTANT

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

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