FDA 510(k) Premarket Notification

CLEARED

K230176 Upper Arm Blood Pressure Monitor

Jun 29, 2023
157 days to decision

K230176 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k230176/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jan 23, 2023
Decision date	Jun 29, 2023
Days to decision	157 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 Co., Ltd.**
Contact	Reanny Wang

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