FDA 510(k) Premarket Notification

CLEARED

K223291 Electronic Blood Pressure Monitor

Jun 14, 2023
231 days to decision

K223291 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k223291/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Oct 26, 2022
Decision date	Jun 14, 2023
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Pango Medical Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Xiaoyun Yang
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**Mid-Link Consulting Co, Ltd.**
Contact	Diana Hong

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