FDA 510(k) Premarket Notification

CLEARED

K230642 Electronic Blood Pressure Monitor

Aug 11, 2023
156 days to decision

K230642 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k230642/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Mar 8, 2023
Decision date	Aug 11, 2023
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Dongguan Kangweile Electronic Technology Co., Ltd.**
Location	Dongguan, CN
Contact	Zhixin Gao
510(k) history	2 submissions · 2 cleared · 2021-2023

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