FDA 510(k) Premarket Notification

CLEARED

K210435 Automatic Arm Electronic Blood Pressure Monitor

May 12, 2021
89 days to decision

K210435 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k210435/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 12, 2021
Decision date	May 12, 2021
Days to decision	89 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Lepu Intelligent Medical Equipment Co., Ltd.**
Location	Shenzhen, CN
Contact	Aaron Lin
510(k) history	3 submissions · 3 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**FDA Regulatory and Quality Systems Consultant**
Contact	Arthur Goddard

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