FDA 510(k) Premarket Notification

CLEARED

K220220 Electronic Sphygmomanometer (Model: LT-P30)

Oct 3, 2022
250 days to decision

K220220 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k220220/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jan 26, 2022
Decision date	Oct 3, 2022
Days to decision	250 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zhuhai Linte Medical Instrument Co., Ltd.**
Location	Zhuhai, CN
Contact	Wallace Huang
510(k) history	2 submissions · 2 cleared · 2021-2022

REGULATORY CONSULTANT

Consulting firm	**Feiying Drug & Medical Consulting Technical Service Group**
Contact	Becky Chen

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