

K192023 Arm Blood Pressure MonitorDec 23, 2019
147 days to decisionK192023 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k192023/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 29, 2019
Decision date	Dec 23, 2019
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Truly Instrument Limited
Location	Shanwei City, Guangdong, CN
Contact	Su HaiSen
510(k) history	5 submissions · 5 cleared · 2008-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k192023/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 27, 2026