

K170545 Automatic Wrist Bluetooth Blood Pressure MonitorNov 21, 2017
270 days to decisionK170545 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k170545/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 24, 2017
Decision date	Nov 21, 2017
Days to decision	270 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Truly Instrument , Ltd.
Location	Shanwei, CN
Contact	Yang Jian-Hao
510(k) history	1 submissions · 1 cleared · 2017-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170545/> 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 31, 2026