

K193386 Wrist Electronic SphygmomanometerJan 27, 2021
418 days to decisionK193386 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k193386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Dec 6, 2019
Decision date	Jan 27, 2021
Days to decision	418 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen Changkun Technology Co., Ltd.
Location	Shenzhen, CN
Contact	Steve Li
510(k) history	5 submissions · 5 cleared · 2020-2023

REGULATORY CONSULTANT

Consulting firm	Guangzhou GLOMED Biological Technology Co., Ltd.
Contact	Cassie Lee

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k193386/> 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 26, 2026