

K212312 RA-T59 Wrist blood pressure monitorJan 27, 2022
188 days to decisionK212312 · Product code: **DXN** · CardiovascularSource: <https://www.510kdatabase.net/k212312/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 23, 2021
Decision date	Jan 27, 2022
Days to decision	188 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Lotusnine Medical Limited
Location	Nantou County, TW
Contact	Yating Chang
510(k) history	1 submissions · 1 cleared · 2022-2022

REGULATORY CONSULTANT

Consulting firm	Puhsu Consulting , Ltd.
Contact	Yuhua Chen

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212312/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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