

**K212171 Electronic Blood Pressure Monitor**Nov 1, 2021  
112 days to decisionK212171 · Product code: **DXN** · CardiovascularSource: <https://www.510kdatabase.net/k212171/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 12, 2021
Decision date	Nov 1, 2021
Days to decision	112 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Dongguan Kangweile Electronic Technology Co., Ltd.</b>
Location	Dongguan, CN
Contact	Zhixin Gao
510(k) history	2 submissions · 2 cleared · 2021-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Reanny Medical Devices Management Consulting Co., Ltd.</b>
Contact	Reanny Wang

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212171/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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