

**K231961 NIBPCuff**Aug 30, 2023  
58 days to decisionK231961 · Product code: **DXQ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k231961/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Jul 3, 2023
Decision date	Aug 30, 2023
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Shenzhen Sino-K Medical Technology Co.,Ltd</b>
Location	Baoan District, Shenzhen, CN
Contact	Lao Chengxin
510(k) history	3 submissions · 3 cleared · 2020-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Shenzhen Choncorut Medical Consulting Co., Ltd.</b>
Contact	Yang Jie

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/k231961/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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