FDA 510(k) Premarket Notification

CLEARED

K253089 NIBP Cuff (BCS-112, BCS-212, BCS-312, BCS-412, BCS-512, BCS-612, BCS-712, BCS-122, BCS-222, BCS-322, BCS-422, BCS-522, BCS-622, BCS-722, BCD-112, BCD-212, BCD-312, BCD-412, BCD-512, BCD-612, BCD-712, BCD-122, BCD-222, BCD-322, BCD-422, BCD-522, BCD-622, BCD-722)

Feb 13, 2026
143 days to decision

K253089 · Product code: **DXQ** · Cardiovascular
Source: https://www.510kdatabase.net/k253089/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Sep 23, 2025
Decision date	Feb 13, 2026
Days to decision	143 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Best Electronics Co., Ltd.**
Location	Shenzhen, CN
Contact	Martin Wong
510(k) history	2 submissions · 2 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Qimmiq Medical Consulting Service Co., Ltd.**
Contact	Yijie You

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