FDA 510(k) Premarket Notification

K242623 Disposable Blood Pressure cuff

CLEARED

Oct 31, 2024
58 days to decision

K242623 · Product code: **DXQ** · Cardiovascular
Source: https://www.510kdatabase.net/k242623/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Sep 3, 2024
Decision date	Oct 31, 2024
Days to decision	58 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Reusable Blood Pressure cuff

APPLICANT

Company	**Shenzhen Medke Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Wei Tao Li
510(k) history	3 submissions · 3 cleared · 2016-2025

REGULATORY CONSULTANT

Consulting firm	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Jie Yang

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