FDA 510(k) Premarket Notification

K182433 Reusable Blood Pressure Cuff, Disposable Blood Pressure Cuff

CLEARED

Dec 17, 2018
102 days to decision

K182433 · Product code: **DXQ** · Cardiovascular
Source: https://www.510kdatabase.net/k182433/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Sep 6, 2018
Decision date	Dec 17, 2018
Days to decision	102 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Shenzhen Caremed Medical Technology Co., Ltd.**
Location	Shenzhen, CN
Contact	Alan Xie
510(k) history	6 submissions · 6 cleared · 2016-2019

REGULATORY CONSULTANT

Consulting firm	**Chonconn Medical Device Consulting Co., Ltd.**
Contact	Kevin Wang

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