FDA 510(k) Premarket Notification

CLEARED

K222652 Aneroid Sphygmomanometer

Nov 28, 2022
88 days to decision

K222652 · Product code: **DXQ** · Cardiovascular
Source: https://www.510kdatabase.net/k222652/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Blood Pressure Cuff (DXQ)
Date received	Sep 1, 2022
Decision date	Nov 28, 2022
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Single Patient Use Aneroid Sphygmomanometer

APPLICANT

Company	**Cardicare Company, Ltd.**
Location	Hangzhou, Zhejiang, CN
Contact	Ying Hao
510(k) history	2 submissions · 2 cleared · 2008-2022

REGULATORY CONSULTANT

Consulting firm	**Irc**
Contact	Charles Mack

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