FDA 510(k) Premarket Notification

K222394 Electronic Sphygmomanometers

CLEARED

Mar 3, 2023
207 days to decision

K222394 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k222394/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Aug 8, 2022
Decision date	Mar 3, 2023
Days to decision	207 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Qingdao Yasee Medical Device Co., Ltd.**
Location	Qingdao, CN
Contact	Shaoju Tian
510(k) history	2 submissions · 2 cleared · 2022-2023

REGULATORY CONSULTANT

Consulting firm	**Regulatory Technology Services, LLC**
Contact	Prithul Bom

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