FDA 510(k) Premarket Notification

CLEARED

K213023 Blood Pressure Monitor(Model:Y30001)

Sep 30, 2022
374 days to decision

K213023 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k213023/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 21, 2021
Decision date	Sep 30, 2022
Days to decision	374 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Zhangzhou Easepal Medical Science and Technology Co., Ltd.**
Location	Zhangzhou, CN
Contact	Yuehua Huang
510(k) history	3 submissions · 3 cleared · 2022-2024

REGULATORY CONSULTANT

Consulting firm	**Guangdong Jianda Medical Technology Co., Ltd.**
Contact	Jett Lee

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