FDA 510(k) Premarket Notification

CLEARED

K210152 Automatic Digital Blood Pressure Monitor

Sep 23, 2021
245 days to decision

K210152 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k210152/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jan 21, 2021
Decision date	Sep 23, 2021
Days to decision	245 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aviche Shandong Medical Technology Co, Ltd.**
Location	Jinan, CN
Contact	Zhike Song
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**Shanghai Truthful Information Technology Co., Ltd.**
Contact	Boyle Wang

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