FDA 510(k) Premarket Notification

CLEARED

K212168 A&D Medical UM-212BLE Blood Pressure Monitor

Oct 6, 2022
451 days to decision

K212168 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k212168/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 12, 2021
Decision date	Oct 6, 2022
Days to decision	451 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**A&D Company, Ltd.**
Location	San Jose, CA, US
Contact	Chanda Melville
Website	http://www.aandd.jp/
510(k) history	7 submissions · 7 cleared · 2011-2022

A&D Company, Ltd. is a diversified manufacturer of precision measurement and medical devices with a manufacturing facility in San Jose, US. The company operates across test and measurement, weighing systems, inspection equipment, and medical device categories. A&D Company has received FDA 510(k) clearances from total submissions, with all cleared devices in the Cardiovascular category. The company's regulatory activity spans from 2011 to 2022. This represents a historical record; no clearances have been submitted in recent years. The company's Cardiovascular device portfo...