

K242193 Arm Type Blood Pressure Monitor (BPM82)Oct 22, 2024
88 days to decisionK242193 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k242193/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jul 26, 2024
Decision date	Oct 22, 2024
Days to decision	88 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avita Corporation
Location	New Taipei City, CN
Contact	Maggie Chao
Website	https://www.avita.com.tw
510(k) history	26 submissions · 26 cleared · 2000-2026

Avita Corporation is a medical device manufacturer based in New Taipei City, China. The company specializes in home care and clinical monitoring devices. Avita has received FDA 510(k) clearances from total submissions since 2000. The company's cleared devices span cardiovascular monitoring, anesthesiology, and general hospital applications. The latest clearance was in 2026, demonstrating continued regulatory activity and product innovation. The company's product portfolio includes blood pressure monitors, pulse oximeters, infrared thermometers, nasal aspirators, nebulizer...