

K033397 AVITA BPM6 SERIES BLOOD PRESSURE METER (OR MONITOR), MODEL BPM6XYApr 9, 2004
168 days to decisionK033397 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k033397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Oct 24, 2003
Decision date	Apr 9, 2004
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Avita Corporation
Location	New Taipei City, CN
Contact	GEO LIN
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...