FDA 510(k) Premarket Notification

CLEARED

K102624 AVITA WRIST TYPE BLOOD PRESSURE MONITOR

Dec 16, 2010
94 days to decision

K102624 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k102624/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Sep 13, 2010
Decision date	Dec 16, 2010
Days to decision	94 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Avita Corporation**
Location	New Taipei City, CN
Contact	JENNIFER REICH
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k102624/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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