

K200346 Wrist Type Blood Pressure MonitorDec 17, 2020
310 days to decisionK200346 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k200346/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 11, 2020
Decision date	Dec 17, 2020
Days to decision	310 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Avita Corporation
Location	New Taipei City, CN
Contact	Amber Dong
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...

REGULATORY CONSULTANT

Consulting firm	Zhengcheng Consulting Corporation
Contact	Anita Chen

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