

K170497 V10Dec 15, 2017
301 days to decisionK170497 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k170497/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 17, 2017
Decision date	Dec 15, 2017
Days to decision	301 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mediana Co., Ltd.
Location	Flintville, TN, US
Contact	Kim Min-hye
510(k) history	10 submissions · 10 cleared · 2005-2020

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k170497/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 18, 2026