

K200434 V20, V20a, AVSM3 SNFOct 9, 2020
228 days to decisionK200434 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k200434/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 24, 2020
Decision date	Oct 9, 2020
Days to decision	228 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	International Regulatory Consultants
Contact	Charlie Mack

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

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