FDA 510(k) Premarket Notification

K170497 V10

CLEARED

Dec 15, 2017
301 days to decision

K170497 · 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