

**K162915 Fully Automatic Electronic Blood Pressure Monitor**Feb 8, 2017  
114 days to decisionK162915 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k162915/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Oct 17, 2016
Decision date	Feb 8, 2017
Days to decision	114 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Andon Health Co, Ltd.</b>
Location	Tiajin, CN
Contact	Liu Yi
510(k) history	92 submissions · 92 cleared · 2008-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k162915/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 1, 2026