

**K182127 Wrist Blood Pressure Monitor Model BP6100**Nov 2, 2018  
88 days to decisionK182127 · Product code: **DXN** · CardiovascularSource: <https://www.510kdatabase.net/k182127/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Aug 6, 2018
Decision date	Nov 2, 2018
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Omron Healthcare, Inc.</b>
Location	Vernon Hills, IL, US
Contact	Renee Thornborough
510(k) history	68 submissions · 67 cleared · 1991-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182127/> 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 May 14, 2026