

**K160557 Full Automatic (NIBP) Blood Pressure Monitor**Jul 6, 2016  
128 days to decisionK160557 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k160557/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Feb 29, 2016
Decision date	Jul 6, 2016
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Health &amp; Life Co., Ltd.</b>
Location	Taipei Hsien, TW
Contact	SARAH SU
510(k) history	60 submissions · 60 cleared · 1999-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160557/> 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 24, 2026