

**K112647 BESTSHAPE BLOOD PRESSURE MONITORING SYSTEM**Nov 22, 2011  
71 days to decisionK112647 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k112647/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                      |
| Submission type       | Traditional   |
| Device classification | System, Measurement, Blood-pressure, Non-invasive (DXN) |
| Date received         | Sep 12, 2011  |
| Decision date         | Nov 22, 2011  |
| Days to decision      | 71 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Wistron Corporation</b>            |
| Location       | Taipei County, TW                     |
| Contact        | TELING HSU                            |
| 510(k) history | 2 submissions · 2 cleared · 2011-2011 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k112647/>; 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 18, 2026