

**K131788 HEALTHSTATS A-PULSE CASPAL + AND MC3100+ MONITORS AND MY-BP BP MANAGEMENT APPLICATION SOFTWARE**Mar 4, 2014  
259 days to decisionK131788 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k131788/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 18, 2013
Decision date	Mar 4, 2014
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Healthstats International Pte. , Ltd.</b>
Location	Eagle, WI, US
Contact	STEPHEN GORSKI
510(k) history	7 submissions · 7 cleared · 2005-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k131788/> 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 30, 2026