

K123498 BP652N (HEM-6300-Z)Mar 21, 2013
128 days to decisionK123498 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k123498/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Nov 13, 2012
Decision date	Mar 21, 2013
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Omron Healthcare, Inc.
Location	Vernon Hills, IL, US
Contact	PAUL DRYDEN
510(k) history	68 submissions · 67 cleared · 1991-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123498/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026