

K113402 SOLOHEALTH STATIONMay 30, 2012
195 days to decisionK113402 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k113402/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Nov 17, 2011
Decision date	May 30, 2012
Days to decision	195 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Solohealth, Inc.
Location	Duluth, GA, US
Contact	STEPHEN KENDIG
510(k) history	1 submissions · 1 cleared · 2012-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k113402/> 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 June 14, 2026