

K081654 HEM-9000AIOct 10, 2008
120 days to decisionK081654 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k081654/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Jun 12, 2008
Decision date	Oct 10, 2008
Days to decision	120 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

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