

K163045 Omron HEM-6400T-Z Wrist Blood Pressure MonitorFeb 21, 2017
113 days to decisionK163045 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k163045/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Oct 31, 2016
Decision date	Feb 21, 2017
Days to decision	113 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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