

K153557 ABPM 7100, Hypertension Management SoftwareJul 19, 2016
218 days to decisionK153557 · Product code: **DXN** · Cardiovascular
Source: <https://www.510kdatabase.net/k153557/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	Dec 14, 2015
Decision date	Jul 19, 2016
Days to decision	218 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	I.E.M. GmbH
Location	Bonita Springs, FL, US
Contact	Hella Witt
510(k) history	5 submissions · 5 cleared · 2004-2016

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