

**K201332 Meditech ABPM-06 (BP6)**Feb 10, 2021  
267 days to decisionK201332 · Product code: **DXN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k201332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Measurement, Blood-pressure, Non-invasive (DXN)
Date received	May 19, 2020
Decision date	Feb 10, 2021
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Meditech , Ltd.</b>
Location	Budapest, HU
Contact	Gabor Kazi
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Arazy Group Consultants, Inc.</b>
Contact	Ray Kelly

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k201332/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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