FDA 510(k) Premarket Notification

K201332 Meditech ABPM-06 (BP6)

CLEARED

Feb 10, 2021
267 days to decision

K201332 · Product code: **DXN** · Cardiovascular
Source: https://www.510kdatabase.net/k201332/

SUBMISSION DETAILS

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

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

REGULATORY CONSULTANT

Consulting firm	**Arazy Group Consultants, Inc.**
Contact	Ray Kelly

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