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510(k) Premarket Notification



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Device Classification Name	System, Measurement, Blood-Pressure, Non-Invasive ²²
510(k) Number	K071960
Device Name	MEDITECH AMBULATORY BLOOD PRESSURE MONITOR, MODEL ABPM-05
Applicant	MEDITECH KFT. INDUSTRIAL PARK 13 M.P. MISGAV MIZPE AVIV, IL 20187
Applicant Contact Correspondent	BENNY ARAZY MEDITECH KFT. INDUSTRIAL PARK 13 M.P. MISGAV MIZPE AVIV, IL 20187
Correspondent Contact	BENNY ARAZY
Regulation Number	870.1130 ²³
Classification Product Code	DXN ²⁴
Date Received	07/16/2007
Decision Date	08/03/2007
Decision	Substantially Equivalent (SESE)
Regulation Medical Specialty	Cardiovascular
510k Review Panel	Cardiovascular
Statement	Statement ²⁵
Type	Special
Reviewed by Third Party	No
Combination Product	No

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