

510(k) Premarket Notification



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Device Classification Name	Electrocardiograph
510(K) Number	K080884
Device Name	QHRV 1 - HEALTH ASSESSMENT SYSTEM
Applicant	MEDTECHS, LLC 111 Beaver Dam Run Durham, NC 27703
Contact	Meghan Ath
Regulation Number	870.2340
Classification Product Code	DPS
Date Received	03/31/2008
Decision Date	04/11/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Summary	Summary
Type	Traditional
Reviewed By Third Party	Yes
Expedited Review	No