

## 510(k) Premarket Notification



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