




[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵

510(k) Premarket Notification

 [6](#) [510\(k\)](#)⁷ | [DeNovo](#)⁸ | [Registration & Listing](#)⁹ | [Adverse Events](#)¹⁰ | [Recalls](#)¹¹ | [PMA](#)¹² | [Classification](#)¹³ | [Standards](#)¹⁴
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[21](#)¹⁵ | [Products](#)¹⁶ | [Assembler](#)¹⁷ | [Reports](#)¹⁸

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Device Classification Name [Computer, Diagnostic, Programmable](#)²²
510(K) Number K992703
Device Name CARDIOTRON EKG MULTI-PHASE INFORMATION ANALYSIS SYSTEM, MODELS 3800, 6800, 8800
Original Applicant PREMIER HEART, LLC.
 601 13th Street, N.w.
 Suite 901 South
 Washington, DC 20005
Original Contact William D Hare
Regulation Number [870.1425](#)²³
Classification Product Code [DQK](#)²⁴
Date Received 08/12/1999
Decision Date 03/21/2000
Decision Substantially Equivalent (SESE)
Regulation Medical Specialty Cardiovascular
510k Review Panel Anesthesiology
Summary [Summary](#)²⁵
Type Traditional
Reviewed By Third Party No
Combination Product No

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5. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/default.htm>
6. </scripts/cdrh/devicesatfda/index.cfm>
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8. </scripts/cdrh/cfdocs/cfpmn/denovo.cfm>
9. </scripts/cdrh/cfdocs/cfRRL/rl.cfm>
10. </scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm>
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14. </scripts/cdrh/cfdocs/cfStandards/search.cfm>

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17. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
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Page Last Updated: 09/29/2014

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13. /scripts/cdrh/cfdocs/cfPCD/classification.cfm

14. [/scripts/cdrh/cfdocs/cfStandards/search.cfm](#)
15. [/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm](#)
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