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510(k) Premarket Notification

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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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Page Last Updated: 09/29/2014

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