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510(k) Premarket Notification Database

Device Classification Name	Electrocardiograph
510(k) Number	K071168
Device Name	THE PORTABLE ANSISCOPE
Applicant	DYANSYS, INC. 8 Snowberry Court Orinda, CA 94563
Contact	Michael A Daniel
Regulation Number	870.2340
Classification Product Code	DPS
Date Received	04/27/2007
Decision Date	08/31/2007
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Cardiovascular
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 10/07/2008

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