

Device Classification Name	electrocardiograph
510(k) Number	K963198
Device Name	PS-41 6M PATIENT SIMULATOR METRON U.S., INC.
Applicant	1345 monroe, n.w., #255a grand rapids, MI 49505
Contact	jim quinn
Regulation Number	870.2340
Classification Product Code	DPS
Date Received	08/15/1996
Decision Date	03/05/1997
Decision	substantially equivalent (SE)
Classification Advisory Committee	Cardiovascular
Review Advisory Committee	Anesthesiology
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No