510(k) Premarket Notification Database

Device Classification Name	catheter, urethral
510(k) Number	K031409
Device Name	URINARY CATHETERS
Applicant	PROMEDIC, INC. 6329 west waterview ct. mccordsville, IN 46055 950
Contact	paul dryden
Regulation Number	876.5130
Classification Product Code	GBM
Date Received	05/05/2003
Decision Date	06/17/2003
Decision	substantially equivalent (SE)
Classification Advisory Committee	Gastroenterology/Urology
Review Advisory Committee	Gastroenterology/Urology
Statement/Summary/Purged Status	Summary only
Type	Traditional
Reviewed by Third Party	No
Expedited Review	No

Database Updated 03/06/2009

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