

510(k) Premarket Notification Database

Device Classification Name	Sterilant, Medical Devices
510(K) Number	K061356
Device Name	POLYURETHANE INFUSION CATHETER, ALPHA CATH, MODEL ADVANCED INFUSION, INC.
Applicant	920 East University Dr. Suite D202 Tempe, AZ 85281
Contact	James Christensen
Regulation Number	880.6885
Classification Product Code	MED
Date Received	05/15/2006
Decision Date	07/03/2006
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No