

510(k) Premarket Notification Database

Device Classification Name	Pump, Infusion, Elastomeric
510(K) Number	K021964
Device Name	ALPHA INFUSION PUMP AND CATHETERS
Applicant	ADVANCED INFUSION, INC. 6200 South McClintock #6 Tempe, AZ 85283
Contact	James Christensen
Regulation Number	880.5725
Classification Product Code	MEB
Date Received	06/14/2002
Decision Date	08/12/2002
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