

510(k) Premarket Notification Database

Device Classification Name	<u>Pump, Infusion, Elastomeric</u>
510(K) Number	K071532
Device Name	ALPHA INFUSION PUMP, MODEL A200, A450
Applicant	ADVANCED INFUSION, INC. 466 West Arrow Hwy., Unit H San Dimas, CA 91773
Contact	James Christensen
Regulation Number	<u>880.5725</u>
Classification Product Code	<u>MEB</u>
Date Received	06/08/2007
Decision Date	02/19/2008
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General Hospital
Statement/Summary/Purged Status	Summary Only
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No