

510(k) Premarket Notification



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Device Classification Name	Lavage, Jet
510(K) Number	K082858
Device Name	EXSEPT WC ANTIMICROBIAL SKIN AND WOUND CLEANSER
Applicant	ALCAVIS INTERNATIONAL, INC. 8322 Helgerman Court Gaithersburg, MD 20877
Contact	Gary J Mishkin
Regulation Number	880.5475
Classification Product Code	FQH
Date Received	09/29/2008
Decision Date	05/27/2009
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	General Hospital
Review Advisory Committee	General & Plastic Surgery
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No