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510(k) Premarket Notification Database

Device Classification Name	Campylobacter Pylori
510(K) Number	K934863
Regulation Number	866.3110
Device Name	Flexsure Hp
Applicant	Smith Kline Diagnostics, Inc. 225 Baypointe Pkwy. San Jose, CA 95134 1622
Contact	Michael A Daniel
Product Code	LYR
Date Received	10/12/1993
Decision Date	05/18/1994
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Microbiology
Review Advisory Committee	Microbiology
Statement/Summary/Purged Status	Summary Only
Type	Traditional
Reviewed By Third Party	No

Database Updated 1/05/2004

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