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510(k) Premarket Notification Database

Device Classification Name	Endoscope And/Or Accessories
510(K) Number	K062875
Regulation Number	876.1500
Device Name	ENDOGASTRIC STOMAPHYX DEVICE AND ACCESSORIES ENDOGASTRIC SOLUTIONS, INC.
Applicant	8210 154th Ave. Ne Redmond, WA 98052
Contact	Michael A Daniel
Classification Product Code	KOG
Date Received	09/28/2006
Decision Date	03/09/2007
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Gastroenterology/Urology
Review Advisory Committee	Gastroenterology/Urology
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 5/08/2007

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