510(k) Premarket Notification Database

Device Classification Name	Resectoscope
510(K) Number	K962506
Regulation Number	876.1500
Device Name	[Specialized Tissue Aspirating Resectoscope (Star
Applicant	Gynecare Innovation Center 1221 Innsbruck Dr. Sunnyvale, CA 94089
Contact	Michael A Daniel
Product Code	FJL
Date Received	06/27/1996
Decision Date	09/16/1996
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Gastroenterology
Review Advisory Committee	Gastroenterology
Statement/Summary/Purged Status	Summary Only
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 1/05/2004