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510(k) Premarket Notification Database

Device Classification Name	Laparoscope, Gynecologic (And Accessories)
510(K) Number	K954775
Regulation Number	884.1720
Device Name	Flo-Stat Fluid Monitoring System
Applicant	Gynecare Innovation Center 1221 Innsbruck Dr. Sunnyvale, CA 94089
Contact	Michael A Daniel
Product Code	HET
Date Received	10/17/1995
Decision Date	05/10/1996
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	Obstetrics/Gynecology
Statement/Summary/Purged Status	Statement/Purged 510(K)
Type	Traditional
Reviewed By Third Party	No

Database Updated 1/05/2004

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