510(k) Premarket Notification Database

Device Classification Name	Hysteroscope (And Accessories)
510(K) Number	K954648
Regulation Number	884.1690
Device Name	Femrx Operastar System
Applicant	Gynecare Innovation Center 1221 Innsbruck Dr. Sunnyvale, CA 94089
Contact	Michael A Daniel
Product Code	HIH
Date Received	10/10/1995
Decision Date	03/14/1996
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	Obstetrics/Gynecology
Statement/Summary/Purged Status	Statement Only
Type	Traditional
Reviewed By Third Party	No

Database Updated 1/05/2004