510(k) Premarket Notification Database

Device Classification Name	Laparoscope, Gynecologic (And Accessories)
510(K) Number	K963872
Regulation Number	884.1720
Device Name	Femrx Morcellator System
Applicant	Gynecare Innovation Center 1221 Innsbruck Dr. Sunnyvale, CA 94089
Contact	Michael A Daniel
Product Code	HET
Date Received	09/26/1996
Decision Date	01/17/1997
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Obstetrics/Gynecology
Review Advisory Committee	Obstetrics/Gynecology
Statement/Summary/Purged Status	Summary/Purged 510(K)
Summary	Summary
Type	Traditional
Reviewed By Third Party	No
Expedited Review	No

Database Updated 1/05/2004