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510(k) Premarket Notification Database

Device Classification Name	Coagulator-Cutter, Endoscopic, Unipolar (And Accessories)
510(K) Number	K964441
Regulation Number	884.4160
Device Name	Femrx Focused Monopolar (Fap) Operastar System [O]
Applicant	Gynecare Innovation Center 1221 Innsbruck Dr. Sunnyvale, CA 94089
Contact	Michael A Daniel
Product Code	KNF
Date Received	11/06/1996
Decision Date	03/28/1997
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

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