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### 510(k) Premarket Notification Database

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

Database Updated 1/05/2004

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